IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOS. 15-3559, 15-3591, 15-3681 & 15-3682

In re Wellbutrin XL Antitrust Litigation

Aetna Health of California Inc. et al.,
Plaintiffs-Appellants,

v.

SmithKlineBeecham Corp. et al.,
Defendants-Appellees.

On Appeal from the United States District Court
For the Eastern District of Pennsylvania (Nos. 2-08-cv-2431, 2-08-cv-2433)

BRIEF OF FEDERAL TRADE COMMISSION AS AMICUS CURIAE IN SUPPORT OF NO PARTY

Deborah L. Feinstein
Director

Markus H. Meier
Acting Deputy Director

Bradley S. Albert
Deputy Assistant Director

Daniel W. Butrymowicz
Elizabeth R. Hilder
Jamie R. Towey
Attorneys
Bureau of Competition
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue NW
Washington, DC 20580

David C. Shonka
Acting General Counsel

Joel Marcus
Director of Litigation

Mark S. Hegedus
Attorney
Office of the General Counsel
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue NW
Washington, DC 20580
202-326-2115
mhegedus@ftc.gov

Attorneys for Federal Trade Commission

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INTRODUCTION

In *FTC v. Actavis*, the Supreme Court ruled that when the holder of a pharmaceutical patent pays a generic patent challenger to stay off the market, such a "reverse payment" must be analyzed under the traditional antitrust rule of reason. 133 S. Ct. 2223, 2237 (2013). Antitrust scrutiny is required because such payments to potential competitors may "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 2236. The Court explained that "the relevant anticompetitive harm" from this type of agreement is that it "prevent[s] the risk of competition." *Id. Actavis* thus reflects the established antitrust principle that "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 220 (3d ed. 2010).

The anticompetitive harm identified in *Actavis* can arise not just when the parties terminate the patent litigation, but also when the brand-name firm pays the generic not to enter during the pendency of the litigation. Sellers of brand-name prescription drugs often enjoy considerable monopoly profits until generic entry, and thus have an incentive to avoid such entry whenever possible. Here, GlaxoSmithKline (GSK), the brand-name company, allegedly paid millions of dollars to Teva, the generic, to stay out of the market for the antidepressant drug

Wellbutrin XL while their patent litigation remained pending. The district court concluded incorrectly that the rule-of-reason principles that *Actavis* articulated do not apply to this reverse-payment agreement because, unlike in *Actavis*, the parties did not settle the underlying patent litigation. While this brief takes no position on the ultimate merits of the case, it addresses four fundamental legal errors in the district court's rule-of-reason analysis.

First, the district court erroneously concluded that the settlement challenged here did not "present[] the type of anticompetitive harm contemplated by *Actavis*" because, unlike that case, the underlying patent litigation continued. Op. 46.[1] In fact, *Actavis* teaches that a reverse payment is likely to be anticompetitive if it shares monopoly profits to "prevent the risk of competition." This concern exists when a reverse payment induces a generic challenger to defer entering the market while the patent case is pending.

Second, the district court held that under the "traditional rule of reason," the plaintiffs could show an antitrust violation only if they proved "that the Wellbutrin Settlement actually resulted in the delayed entry of Wellbutrin XL" into the market. Op. 52-53. But the rule-of-reason inquiry considers whether the nature of

[1] The district court's opinion (op.) is Document 612 on that court's docket.

the restraint is likely to harm competition. It requires no showing of actual delayed entry or injury to a specific party to establish an antitrust violation.

Third, the district court erred when it credited the defendants' proffered procompetitive justifications without requiring them to explain how the benefits are attributable to the reverse payment. Indeed, it is implausible that Teva would have required a payment to accept beneficial terms, or that GSK would have paid Teva to accept such benefits.

Fourth, the district court further erred when it found the agreement lawful based in part on a provision that entitled the parties to abandon their deal if the FTC objected to it. The court mistook that provision as an effective grant of veto power to the FTC. More importantly, such provisions have no relevance to the rule-of-reason inquiry, for they shed no light on the likely competitive effects of the alleged restraint.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC, an independent federal agency charged with promoting a competitive marketplace and protecting consumer interests, exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry. The Commission has issued a variety of empirical studies addressing the competitive process by which generic substitution for brand-name drugs saves consumers

billions of dollars each year,[2] and has used its law enforcement authority to challenge anticompetitive patent settlements.[3] Pursuant to Fed. R. App. P. 29(a), the Commission respectfully submits this brief.

STATEMENT OF THE CASE

A. Background

The entry of generic drugs into the market is governed by a regulatory framework known as the Hatch-Waxman Amendments.[4] The basic contours of that framework are set forth in this Court's opinion in *Lamictal*, 791 F.3d at 394-96. Three features of the regime are particularly relevant here.

The first concerns the circumstances under which a would-be generic competitor can enter the market "at risk"—*i.e.*, while patent infringement issues

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[2] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) ("*AG Report*"), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (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. Both the Supreme Court and this Court have relied on such FTC studies. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 n.21 (3d Cir. 2015) ("*Lamictal*").

[3] *See, e.g.*, *Actavis*, 133 S. Ct. 2223; *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 411 (E.D. Pa. 2015).

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (1984) (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code).

are unresolved. The Hatch-Waxman Amendments enable a generic company to litigate a patent challenge before it enters the market. When the generic company files an Abbreviated New Drug Application (ANDA) with the FDA, it may certify that its product does not infringe any existing, valid patent (this action is called a "paragraph-IV certification"). The Amendments deem the paragraph-IV certification to be an artificial act of infringement and allow the brand-name manufacturer to promptly sue the generic applicant. A timely suit automatically stays FDA approval of the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). The stay immediately terminates, however, if a court rules that the patent at issue is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii)(I). Once the stay terminates and the FDA approves the ANDA, the generic can enter the market (unless the patentee obtains a preliminary injunction).

The Hatch-Waxman Amendments thus permit a generic competitor to enter the market at risk. A company that chooses to enter at risk and is later held to have infringed the patent may be liable for substantial damages. The decision to enter at risk therefore reflects in part the generic drug applicant's estimation of the strength of its patent-infringement defense. By the time of the settlement in this case, Teva had already launched one version of the product at issue at risk.

Second, under the Hatch-Waxman Amendments, the first generic to file an ANDA with a paragraph-IV certification is eligible for a 180-day exclusivity

period in which it can sell its product without competition from other generic firms. *See Lamictal*, 791 F.3d at 396. But the brand-name manufacturer is still allowed during this period to sell its own "authorized generic," which is the brand-name drug marketed as a generic. *Id.* This Court recently held that a commitment by the brand-name manufacturer not to introduce its own authorized generic to compete against the generic manufacturer—referred to as a "no-AG agreement"—can amount to a reverse payment that "may be subject to antitrust scrutiny under the rule of reason." *Id.* at 403.

Third, parties to settlements of pharmaceutical patent litigation under the Hatch-Waxman Amendments must submit their settlement agreements to the FTC and the Department of Justice. Congress imposed that requirement because it was concerned about "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 107-167, at 4 (2002). *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified at 21 U.S.C. § 355 note). The MMA facilitates law enforcement by providing access to all reverse-payment deals. But Congress placed no duty on the FTC or the DoJ to take action on a submitted settlement. To the contrary, the MMA provides that "any failure … to take action" concerning a filed agreement

"shall not at any time bar any proceeding or any action with respect to" any such agreement. *Id*. at § 1117, 117 Stat. 2463.

The Commission reviews agreements filed pursuant to the MMA.[5] Staff sometimes takes further action, ranging from informal inquiries into settlement terms to formal investigations that may result in an enforcement action. As with enforcement matters generally, these decisions are made on a case-by-case basis. Importantly, a determination not to investigate or challenge an agreement does not signify an implicit approval of the agreement or a lack of antitrust concern.

B. The Challenged Agreements

GSK manufactures the brand-name drug Wellbutrin XL, an extended-release version of the antidepressant bupropion hydrochloride. GSK's business partner, Biovail, owns rights to patents covering Wellbutrin XL. Op. 10. In September 2004, Anchen Pharmaceuticals, Inc. filed the first ANDA with a paragraph-IV certification for a generic version of Wellbutrin XL. Op. 12. Anchen was therefore eligible for a 180-day period during which other ANDA filers (but not an authorized generic) would be precluded from competing. GSK and Biovail sued

[5] *See generally* Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, https://www.ftc.gov/system/files/attachments/competition-policy-guidance/050210pharmrulesfaqsection.pdf (last visited Mar. 10, 2016).

Anchen for patent infringement in December 2004, triggering the automatic 30-month stay on FDA approval of Anchen's ANDA. *Id*.

In August 2006, the district court hearing the patent case entered a final judgment that Anchen's generic product did not infringe Biovail's patent. Op. 15. Biovail appealed the decision to the Federal Circuit. Op. 15-16.[6] In the meantime, the district court's holding of non-infringement terminated the stay on FDA approval of Anchen's ANDA, which FDA approved in December 2006. Op. 20.

Pursuant to an agreement with Anchen, Teva immediately began selling 300-mg generic Wellbutrin XL. Op. 19-20 & n.10. This launch was "at risk" because Biovail still had pending claims of patent infringement. Op. 25-27. Anchen and Teva also anticipated launching a 150-mg version at risk as early as the first quarter of 2007. Op. 20.

In February 2007, however, Teva and Anchen abandoned their plan to launch 150-mg generic Wellbutrin XL at risk. Instead, they entered into the agreements with GSK and Biovail that are the subject of this appeal. Under those agreements, Teva and Anchen committed not to sell 150-mg generic Wellbutrin XL for more than a year—until a licensed entry date of May 30, 2008—unless Anchen won the patent appeal before then. Op. 26. GSK agreed not to market an

[6] By the time of the appeal, GSK had withdrawn from the patent suit. Op. 12.

authorized generic during the first 180 days after Teva began to sell either 150-mg or 300-mg generic Wellbutrin XL. Op. 27. Finally, the parties agreed that, if the FTC objected within a defined time period, they would "either resolve the objection or have the right to terminate the entire settlement." Op. 66.

C. Proceedings Below

Direct and indirect purchaser plaintiffs sued Biovail and GSK for conspiring to prevent generic competition, including by entering into anticompetitive reverse-payment agreements with generic drug manufacturers. Op. 34-35. The district court granted summary judgment in favor of the defendants, holding that no reasonable jury could find the challenged reverse-payment agreement unlawful. The court acknowledged GSK's no-AG commitment, found that Teva had insisted on this provision, and did not question that it was worth hundreds of millions of dollars to Teva. Op. 27, 46 n.28, 54, 63. But notwithstanding Teva's agreement to stay out of the market, the court interpreted *Actavis* to have adopted a "limited definition" of the competitive harm that justifies antitrust scrutiny of reverse payments. It concluded that *Actavis* did not apply to this reverse-payment settlement because the patent challenge continued, so the settlement "maintain[ed] the risk of a finding of patent invalidity or non-infringement." Op. 41-42. The court reasoned that, because the settlement allowed the patent litigation to continue, it was distinguishable from the settlement reviewed in *Actavis* and was

comparable to one without a reverse payment at all. Op. 42-43. In the court's view, continued litigation meant that "the patent's strength dictated the entry date for generic Wellbutrin XL," op. 43, notwithstanding Teva's insistence on a payment.

After finding that *Actavis* did not apply, the court then assessed the agreement under what it called the "traditional rule of reason." *See, e.g.*, op. 44-48, 50 n.32, 52. According to the court, this required plaintiffs to "show that the Wellbutrin Settlement actually resulted in the delayed entry of Wellbutrin XL—that absent the Wellbutrin Settlement, generic competition would have occurred earlier." Op. 52-53. Ruling that the plaintiffs had failed to provide such evidence, the court held that no reasonable jury could find the challenged reverse-payment agreement to be anticompetitive. Op. 44, 54-56.

The court also held that, even if the plaintiffs could show anticompetitive effects, "a reasonable jury could not find that any anticompetitive effects outweigh the procompetitive benefits of the settlement." Op. 5; *see also* op. 57-58. The court deemed as procompetitive certain benefits that GSK had granted to Teva and Anchen that could facilitate generic entry. Op. 57-62. Having credited GSK's testimony that Teva would not have settled without the no-AG commitment, the court held this challenged reverse payment was necessary to achieve these proffered procompetitive benefits. Op. 63. It did not, however, explain why Teva would insist on being paid before it would accept help entering the market.

Finally, the court also deemed settlement provisions relating to FTC review of the agreements to be relevant to its rule-of-reason analysis. Op. 64-67. The court explained that the parties could terminate the settlement if the FTC objected to it and, after good-faith efforts, they were unable to address the agency's concern. Op. 66. In the court's view, this reservation of a right to terminate "in effect" gave the FTC "veto power over the Wellbutrin Settlement." Op. 66. As a result, the court suggested, the FTC review provisions had procompetitive benefits "at least in an indirect way," because "the FTC, therefore, did not have to use their limited resources to file a lawsuit to force changes to the agreement or even abrogation of it." *Id.*; *see also id.* n.40. In addition, the court ruled, these "enhanced FTC review" provisions "tend to negate any anticompetitive aim of the parties, in particular GSK." Op. 66.

ARGUMENT

I. THE DISTRICT COURT MISUNDERSTOOD THE ANTICOMPETITIVE HARM SHOWING REQUIRED IN REVERSE-PAYMENT CASES

The district court's holding that no reasonable jury could find that the Wellbutrin settlement agreement had any anticompetitive effect rests on two legal errors. First, the court's conclusion that *Actavis* does not apply to a reverse payment that does not terminate the underlying patent litigation turns on an untenably narrow view of the competitive concern identified by the Supreme Court. *Actavis* reflects antitrust law's fundamental concern with collusive

arrangements by potential rivals that agree to avoid competition and share the resulting monopoly profits. This core antitrust concern can arise whenever a pharmaceutical company pays a potential generic rival to stay out of the market, whether or not patent litigation is still pending.

Second, the district court erroneously held that plaintiffs could establish an antitrust violation under a traditional rule-of-reason analysis only if they "show[ed] that the Wellbutrin Settlement actually resulted in the delayed entry." Op. 52-53. In fact, the traditional rule of reason requires a plaintiff to show conduct that threatens harm to the competitive process and sufficient market power to inflict such harm; it does not require proof of the "but-for" world—what the market would have looked like in the absence of the anticompetitive conduct. In holding to the contrary, the district court improperly conflated the analysis of an antitrust *violation* with the distinct question of antitrust *standing*. A private plaintiff seeking damages must show that it suffered an injury-in-fact caused by the violation. The government faces no such requirement. Obscuring that distinction threatens to impede government law-enforcement actions.

A. Eliminating the Risk of Competition is an Anticompetitive Harm Under *Actavis* Even if Patent Litigation Remains Ongoing

In *Actavis*, the Supreme Court examined a patent litigation settlement between a brand-name drug manufacturer and a would-be generic entrant. The Court found the settlement "unusual" because "a party with no claim for damages

… walks away with money simply so it will stay away from the patentee's market." *Actavis*, 133 S. Ct. at 2231, 2233. Such "reverse payments," the Court held, "tend to have significant adverse effects on competition," *id.* at 2231, because they "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 2236. In other words, reverse-payment settlements "prevent the risk of competition." *Id*.

The core concern in *Actavis* was that a monopolist and a potential competitor would collude to avoid competing for some period of time and share the resulting monopoly profits. *See id.* at 2235. The Court thus focused on the companies' reasons for making the reverse payment: "If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2237.

The decision below emphasized repeatedly that Teva had insisted on a no-AG agreement as part of any settlement. Op. 27-28, 54-55. The court further noted this Court's recent holding that "a no authorized generic agreement 'falls under *Actavis*'s rule because it may well represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of

competition.'" Op. 37 n.25 (quoting *Lamictal*, 791 F.3d at 393). Indeed, the court did not question plaintiffs' allegation that GSK's no-AG agreement amounted to a $200 million payment to Teva; it simply deemed that fact irrelevant. Op. 46 n.28. Finally, the court observed that "a reasonable jury [could] find that Anchen/Teva would have launched at risk after June 2007," op. 84, and that they agreed in the settlement to delay competition until Anchen prevailed in the Federal Circuit, or May 30, 2008, whichever occurred first.

The court nevertheless held that the settlement "d[id] not present the same antitrust concerns that motivated the court in *Actavis*" because it "required the underlying patent litigation to continue, maintaining the risk of a finding of patent invalidity or non-infringement and providing for immediate generic entry upon such a finding." Op. 41; *see also* op. 46-47. The court therefore did not examine the purpose of GSK's no-AG commitment to Teva or consider whether that payment induced Teva to agree not to launch at risk, thereby maintaining GSK's otherwise uncertain 150-mg Wellbutrin XL monopoly profits while the patent case remained pending.

In reaching that conclusion, the district court ignored the reasoning of *Actavis*. To be sure, the Supreme Court in *Actavis* found that a reverse payment can be anticompetitive if it settles a patent challenge and thereby eliminates the risk that the underlying patent will be held invalid or not infringed. But the Court

never suggested that the risk of losing the patent case was the *only* cognizable risk of competition a reverse payment might seek to avoid. Rather, the reasoning of *Actavis* extends to any situation where a monopolist makes a reverse payment to "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Actavis*, 133 S. Ct. at 2236. An agreement that forecloses the possibility of at-risk entry into the market (in exchange for shared monopoly profits) can also be anticompetitive under that analysis.

In overlooking the underlying logic of *Actavis*, the district court elevated nominal factual distinctions over economic reality. In *Lamictal*, this Court reversed the district court for the same analytical error. There, relying on multiple references in *Actavis* to "money," the district court concluded that *Actavis* was limited to payments of cash and did not address equally valuable non-cash compensation. This Court held instead that as a matter of economic reality "no-AG agreements are likely to present the same types of problems as reverse payments of cash." *Lamictal*, 791 F.3d at 404. This Court further explained that it did not believe the *Actavis* court "intended to draw such a formal line," citing the well-established proposition that "economic realities rather than a formalistic approach must govern review of antitrust activity." *Id.* at 406 & n.24 (quoting *United States v. Dentsply Int'l*, 399 F.3d 181, 189 (3d Cir. 2005)).

The alleged reverse payment in this case is "likely to present the same types of problems" (*Lamictal*, 791 F.3d at 404) as the payment analyzed in *Actavis*. GSK allegedly gave Teva something of great value—a six-month monopoly on generic sales of Wellbutrin XL worth millions of dollars—at significant cost to itself. In the same agreement, Teva, which could have entered the market at any time, agreed to stay out pending the patent appeal, thus safeguarding GSK's profits. This raises the prospect that the payment may have been designed "to maintain and to share patent-generated monopoly profits." *Actavis*, 133 S. Ct. at 2237.

B. Proof of Actual Delayed Entry is Not Required to Show Anticompetitive Effects

The district court held that "[i]t is in keeping with the traditional rule of reason analysis to require the plaintiffs to show that the Wellbutrin Settlement actually resulted in the delayed entry of Wellbutrin XL—that absent the Wellbutrin Settlement, generic competition would have occurred earlier." Op. at 52-53.[7] It then ruled that plaintiffs had failed to produce evidence supporting either of two potential but-for scenarios—that the parties would have agreed to an earlier entry date or that continued litigation would have resulted in earlier entry because Teva

[7] The district court appears to suggest that the *Actavis* analysis is somehow different from the traditional rule of reason. But in *Actavis*, the Supreme Court made clear that the "FTC must prove its case as in other rule-of-reason cases." 133 S. Ct at 2237. Thus, *Actavis* does not redefine the general antitrust rule of reason, but simply applies it. *Lamictal*, 791 F.3d at 411.

would have launched at risk. Op. 56. The district court erred in holding that a plaintiff can show an antitrust violation under the rule-of-reason analysis only if it shows what actually would have occurred in the market absent the anticompetitive conduct.

To prevail under the rule of reason, an antitrust plaintiff must demonstrate that a challenged agreement has anticompetitive effects. The Supreme Court has long recognized that proving anticompetitive effects does not require reconstructing the hypothetical world absent the conduct. Instead, the analysis focuses on whether an agreement "promotes competition or … suppresses competition." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 691 (1978).

Of course, anticompetitive effects *can* be established by demonstrating an actual increase in prices or decrease in output. *See, e.g.*, *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). But the Supreme Court has condemned practices that "impede the ordinary give and take of the market place," *Prof'l Eng'rs*, 435 U.S. at 692, or were "likely enough to disrupt the proper functioning of the price-setting mechanism of the market … even absent proof that [they] resulted in higher prices." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 461-62 (1986). The Court has focused on "the principal tendency of a restriction" to interfere with competition. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999);

see also Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918) (courts should examine "the nature of the restraint and its effect, actual or probable"). Similarly, in a reverse-payment case, anticompetitive effects are established if the payment represents a sharing of the brand's monopoly profits to "prevent the risk of competition"—whether or not that competition would have ultimately materialized. *Actavis*, 133 S. Ct. at 2236; *see also In re Cipro Cases I & II*, 61 Cal. 4th 116, 150 (2015) (applying parallel state-law provision).

Additional proof is required for a private plaintiff to demonstrate it has antitrust standing to sue under the Clayton Act. To be entitled to damages, a private plaintiff must prove not only an antitrust violation, but also that the violation caused actual antitrust injury. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 485-86, 489 (1977). But this inquiry is analytically separate from—and additional to—the showing of harm to competition necessary to establish the underlying antitrust violation.[8] *See id.* at 486, 489 (explaining injury requirement and noting that antitrust laws include "statutory prohibition[s] against acts that have a potential to cause certain harms" and statutory authority for

[8] *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 334.2c, at 330 (1989 Supp.)); *see also Volmar Distribs., Inc. v. New York Post Co.*, 825 F. Supp. 1153, 1161 n.5 (S.D.N.Y. 1993) (under *Atlantic Richfield*, antitrust injury requirement is separate from substantive requirements of Sherman Act).

"damages action[s] intended to remedy those harms"); *Lamictal*, 791 F.3d at 410 n.35 (treating question of antitrust injury as distinct from violation); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 281, 289 (3d Cir. 2012) (same).

The district court's opinion reflects its failure to keep these two analyses separate. It twice examines whether generic Wellbutrin XL would have actually launched in the absence of the settlement agreement: first to determine whether there was an antitrust violation, op. 52-56, and then again to determine whether the plaintiffs satisfied the antitrust standing requirement, op. 78-84.

C. The Distinction Between Anticompetitive Effect and Antitrust Standing is Significant for Government Antitrust Enforcement

In a private damages case, the distinction between antitrust violation and antitrust standing is often academic because private plaintiffs must prove both. The district court's failure to recognize this distinction, however, implicates government antitrust enforcement. Because the FTC, along with the DoJ, enforces the substantive antitrust laws directly, it need not show a specific injury. *See* 15 U.S.C. § 45(a)(2); *California v. Am. Stores Co.*, 495 U.S. 271, 295-96 (1990) ("In a Government case the proof of the violation of law may itself establish sufficient public injury to warrant relief."); 2 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 303, at 61 (4th ed. 2014). The government can "sue anyone who violates the antitrust laws" and obtain an injunction to block an anticompetitive agreement or conduct. *Zoellner v. St. Luke's Reg'l Med. Ctr., Ltd.*, 937 F. Supp. 2d

1261, 1266 (D. Idaho 2013) (citing *Glen Holly Entm't, Inc. v. Tektronix, Inc.*, 352 F.3d 367, 371 (9th Cir. 2003)).

The distinction between public and private suits is intentional, reflecting the strong public law enforcement interest in allowing the government to redress conduct when "the reasonably anticipated consequence[]" is a "statutorily prohibited injury." 2 Areeda & Hovenkamp, *Antitrust Law* ¶ 303, at 61. The leading antitrust treatise offers a useful analogy:

> [T]he state can interdict drunken driving even when the driver has caused no injury at all in the particular case. Its power results from the fact that drunken driving is known to have harmful consequences and it is less socially costly to arrest the driver before rather than after these consequences occur. The private plaintiff's interest, by contrast, is purely remedial.

Id. at 61-62.

The district court appeared to recognize that the FTC faces a lower burden in a reverse-payment case than private plaintiffs, but it incorrectly characterized the nature and source of the distinction. Op. 72 (the FTC "faces a different standard of causation in bringing agency antitrust actions such as *Actavis*: the FTC must establish only that the defendant's action is '*likely* to cause injury'") (quoting 15 U.S.C. § 45(n)). First, the district court's reference in the decision's antitrust standing section to the "standard of causation" facing the FTC suggests that the FTC must show antitrust standing. But that is not correct because, as just shown,

the FTC enforces the antitrust laws directly pursuant to the FTC Act. *See* 15 U.S.C. § 45(a)(2).

Second, the district court erroneously distinguished government and private plaintiffs on the basis of Section 5(n) of the FTC Act, 15 U.S.C. § 45(n). Op. 72. That section, however, governs only the Commission's authority over "unfair … acts or practices," not its distinct authority to stop "unfair methods of competition." *See* H.R. Rep. No. 103-617 at 12 (1994) (Conf. Rep.), *as reprinted in* 1994 U.S.C.C.A.N. 1795, 1798 (noting that 15 U.S.C. § 45(n) codifies the Commission's Policy Statement on Unfairness (appended to *Int'l Harvester Co.*, 104 F.T.C. 949, 1070, 1072 (1984)), which specifically does not apply to "unfair methods of competition"). Accordingly, Section 5(n) is irrelevant to an FTC case brought under *Actavis*, which alleges only "unfair methods of competition."

II. A REVERSE PAYMENT IS NOT JUSTIFIED BY A PROCOMPETITIVE BENEFIT UNLESS THE DEFENDANT SHOWS HOW THE PAYMENT PROMOTES THAT BENEFIT

The district court held that even if plaintiffs could show anticompetitive effects, the reverse-payment agreement could not violate antitrust law because it had sufficient procompetitive justifications. Op. 62-63. This mistaken conclusion rests on a misunderstanding of the justification inquiry prescribed by the rule of reason.

Under the rule of reason, once a plaintiff shows evidence of anticompetitive effect and market power, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective." *See Brown Univ.*, 5 F.3d at 669. In the reverse-payment context, this means that the defendant must "explain[] the presence of the challenged term and show[] the lawfulness of that term under the rule of reason." *Lamictal*, 791 F.3d at 412 (quoting *Actavis*, 133 S. Ct. at 2236); *see also Cephalon, Inc.*, 88 F. Supp. 3d at 415. The proffered justification cannot be pretextual. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 197 (3d Cir. 2005); *see also Cephalon, Inc.*, 88 F. Supp. 3d at 418-19.

In *Actavis*, the Supreme Court specifically identified two justifications for reverse payments—"litigation expenses saved through the settlement" and "compensation for other services that the generic has promised to perform." 133 S. Ct. at 2236. Such explanations can indicate that the generic's decision not to compete was based on "traditional settlement considerations," thereby refuting the antitrust concern that the parties are sharing monopoly profits preserved by avoiding competition. *Id.* at 2236.

The Court observed that "[t]here may be other justifications" than the two specifically identified. *Id*. But nothing in *Actavis* suggests that it altered traditional rule-of-reason principles governing the assessment of justifications or that a justification can be credited if it lacks any connection to the reverse payment.

Indeed, absent an explanation for the reverse payment, nothing contradicts the conclusion that "the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.*

The district court's justification analysis is thus flawed for several reasons. First, the district court failed to require the defendant to articulate a plausible link between the reverse payment (a no-AG commitment that the court acknowledged could have significant value) and a sufficiently procompetitive objective. The court relied on a number of provisions in the settlement that might assist Teva's getting the generic product to market. Op. 57-58. But the antitrust question is not whether there are benefits to certain provisions in the abstract. It is whether the benefits are attributable to the restraint—in this case the payment. *See Brown Univ.*, 5 F.3d at 669 (restraint must "promote[] a sufficiently pro-competitive objective"). None of the purported procompetitive benefits the district court identified can explain the payment as anything other than an inducement to Teva to share GSK's monopoly profits instead of competing prior to May 2008. Indeed, it defies economic logic and common sense that Teva would insist on a payment to accept terms that unambiguously benefited it by facilitating its generic entry, or that GSK would otherwise pay to accelerate such entry.

Second, the district court erred by finding the agreement justified because it allowed generic entry earlier than otherwise might have been possible. *Actavis* specifically rejected this line of argument. *See* 133 S. Ct. at 2234-35. As this Court explained, "[n]otwithstanding such 'early entry,' the antitrust problem was that … entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Lamictal*, 791 F.3d at 408. Indeed, the "concern with combining an early-entry date with the valuable consideration of a no-AG agreement is that the generic manufacturer may be willing to accept a later early-entry date without any corresponding benefit to consumers." *Id.* at 405 n.23; *see also Actavis*, 133 S. Ct. at 2237 ("They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.").

Finally, the district court's analysis irrationally turns proof of the plaintiff's case—the use of a reverse payment to induce an entry-restricting settlement—into a defense. The district court found that Teva would not have entered the settlement unless GSK shared its monopoly profits through a no-AG commitment. Op. 67. Based on this factual finding, the court concluded that the payment was necessary to achieve the purported procompetitive benefits of the agreement. *Id.* Under *Actavis*, however, that is the very finding that can demonstrate that the parties

intended the reverse payment to eliminate the risk of competition by "maintain[ing] and … shar[ing] patent-generated monopoly profits." *Actavis*, 133 S. Ct. at 2237; *see also Lamictal*, 791 F.3d at 410 (GSK's "agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits …"). Absent the payment, consumers may have benefited from an at-risk launch by Teva. By the district court's flawed logic, the payment was justified by the very thing the Supreme Court found to be anticompetitive.

None of the justifications discussed by the district court explains the alleged no-AG payment as anything other than an inducement to the generic to eliminate the risk of competition prior to an appellate court decision on the patent merits. The court's ruling that these aspects of the settlement could justify any anticompetitive effects of the challenged restraint was legal error.

III. SO-CALLED "ENHANCED FTC REVIEW" PROVISIONS ARE IRRELEVANT TO THE ANTITRUST ANALYSIS

As explained above, the MMA requires drug companies to file their patent settlements and certain other agreements with the FTC and the DoJ. The district court deemed it relevant to a rule-of-reason analysis of a reverse-payment agreement that the Wellbutrin settlement agreement included provisions relating to that statutorily mandated submission that (1) the parties would respond to FTC inquiries and attempt to resolve any FTC objection, and (2) any party could

terminate the settlement if they could not address any FTC objection. Op. 64-65. The court misconstrued these provisions to mean that "[t]he FTC was given, in effect, veto power over the Wellbutrin Settlement," and held that these provisions "tend to negate any anticompetitive aim of the parties, in particular GSK," and "may also be described as procompetitive, at least in an indirect way." Op. 66.[9]

But, as stated by the district court: "If the FTC objected to the settlement, the parties agreed that they would either resolve the objection or have the right to terminate the entire settlement." Op. 66. *See also* op. 32 (GSK had similar rights). From this unremarkable provision granting the parties the right to terminate the settlement, the court concluded that the FTC had "veto power" over it.[10] Op. 66-67 ("the FTC only had to raise concerns to have the agreement changed in a way that

[9] The district court asked the parties, in preparation for argument on the summary judgment issues concerning the challenged agreements, to provide additional information on the procedures applicable to agency review of those agreements. Order, *In re Wellbutrin XL Antitrust Litig.*, 2:08-cv-02431 (E.D. Pa. July 17, 2012), ECF No. 464. The FTC submitted an amicus brief in the district court in September 2013, in part to explain the agency's review of drug patent settlements under the MMA. See Federal Trade Commission's Brief as Amicus Curiae at 19-21, *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-02431, (E.D. Pa. Sept. 26, 2013), ECF No. 510-2. The court rejected the FTC's submission. Order, *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-02431, (E.D. Pa. Oct. 3, 2013), ECF No. 522.

[10] So-called "best efforts" and "termination rights" clauses are common in merger agreements that the parties believe may raise competitive concerns. *See, e.g.*, Darren S. Tucker & Kevin L. Yingling, *Antitrust Risk-Shifting Provisions in Merger Agreements After the Financial Collapse*, Antitrust Source 1, 3 (April 2009), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1397649.

would be more beneficial to consumers."); op. 65 ("A note of concern from the agency was sufficient to alter or terminate the settlement; no formal agency action was necessary.").[11] The reservation of a right to terminate a filed settlement does not mean that it will in fact be terminated if the agency objects.

More fundamentally, the district court's reliance on FTC-related provisions reflects a basic misunderstanding of antitrust principles in three respects.

First, the district court asserted that what it called the "provisions for enhanced FTC review" would "tend to negate any anticompetitive aim of the parties, in particular GSK." It is well established, however, that "a good intention will [not] save an otherwise objectionable" arrangement. *Chi. Bd. of Trade,* 246 U.S. at 238. A party's subjective intent is relevant only to the extent that it helps the court understand the likely effect of the challenged conduct. *See, e.g.*, *id.* (intent evidence may help to "interpret facts and to predict consequences").[12] In the context of reverse payments in particular, *Actavis* explains that "the relevant antitrust question" is how to explain the presence of the payment. 133 S. Ct. at

[11] Agreements filed with the FTC under the MMA are subject to confidentiality protections that limit the agency's ability to disclose the contents of such agreements. This Court, however, will be able to examine the relevant provisions (Section 3 of the Omnibus Agreement) in the sealed portion of the joint appendix.

[12] *See also United States v. Microsoft*, 253 F.3d 34, 59 (D.C. Cir. 2001) (knowledge of intent behind challenged conduct "is relevant only to the extent it helps us understand the likely effect of the monopolist's conduct").

2237. Is the basic reason "to maintain and to share … monopoly profits?" *Id.* Or can the defendants show "legitimate justifications" that can "explain[] the presence of the challenged [reverse-payment] term?" *Id.* at 2236. This inquiry focuses on the competitive effects of the conduct. Provisions in a settlement agreement promising cooperation with an FTC review reveal nothing about the likely competitive effects of the challenged agreement.

Second, the district court's suggestion that the FTC-related provisions provided "indirect procompetitive benefits" likewise is unconnected to the likely effects of the challenged reverse payment. The court reasoned that the veto power the parties purportedly granted the FTC would conserve FTC law enforcement resources. Op. 66. But even if that were correct, as a matter of antitrust law, the potential savings in FTC law enforcement resources cannot possibly offset adverse economic effects on consumers of Wellbutrin XL.

Moreover, the district court's reasoning implicitly assumes that the FTC's decision not to challenge the Wellbutrin settlement amounted to an administrative blessing of the deal.[13] But it is well established that government *inaction* does not

[13] According to the court, merely "a note of concern" from the FTC "was sufficient to alter or terminate the settlement," and the FTC raised no concern. Op. 65. The court thus went beyond its mistaken view of FTC-related provisions, adopting as material facts the settling parties' description of what occurred at an FTC meeting and the identity of agency personnel with whom they interacted. Op. 32-34, 65.

indicate agency *approval*. *See, e.g.*, *Altria Group, Inc. v. Good*, 555 U.S. 70, 89-90 (2008). That is particularly true here, where the MMA makes clear that "any failure of the [FTC] to take action" against a filed settlement agreement "shall not at any time bar any proceeding or any action with respect to" any such agreement. MMA § 1117, 117 Stat. at 2463.

Courts impute no legal significance to agency inaction for good reason. An agency's exercise of its enforcement discretion "involves a complicated balancing" of factors, including "whether a violation has occurred," whether the agency has available enforcement resources, and whether a potential action "best fits the agency's overall policies." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Given those concerns, "the Commission alone is empowered to develop that enforcement policy best calculated to achieve" its statutory mission. *Moog Indus., Inc. v. FTC*, 355 U.S. 411, 413 (1958) (refusing to stay an FTC order against one firm until competing firms could be similarly restrained).

Congress enacted the MMA filing requirements so that the FTC could exercise its enforcement discretion with full knowledge of the universe of potential targets. The MMA was not designed as a pre-clearance review mechanism that immunizes companies' agreements or provides antitrust counseling. The district court committed serious legal error when it turned the MMA into an escape hatch for defendants to evade antitrust scrutiny.

CONCLUSION

Regardless of its ruling on the ultimate merits, this Court should correct the legal errors committed by the district court, as set forth above.

Respectfully submitted,

Deborah L. Feinstein
Director

Markus H. Meier
Acting Deputy Director

Bradley S. Albert
Deputy Assistant Director

Daniel W. Butrymowicz
Elizabeth R. Hilder
Jamie R. Towey
Attorneys
Bureau of Competition
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue NW
Washington, DC 20580

David C. Shonka
Acting General Counsel

Joel Marcus
Director of Litigation

/s/ Mark S. Hegedus
Mark S. Hegedus
Attorney
Office of the General Counsel
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue NW
Washington, DC 20580
202-326-2115
mhegedus@ftc.gov

Attorneys for Federal Trade Commission

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NOS. 15-3559, 15-3591, 15-3681 & 15-3682
In re Wellbutrin Antitrust Litigation
COMBINED CERTIFICATES
BRIEF OF FEDERAL TRADE COMMISSION AS AMICUS CURIAE
IN SUPPORT OF NO PARTY

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. Civ. P. 32(a)(7)(B). It has 6,950 words as counted by Microsoft Word 2010.
2. The electronic version of this brief is identical to the version sent in hard copy to this Court.
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4. I filed the electronic version of this brief with the Court via the CM/ECF system. The Notice of Docket Activity generated by CM/ECF system constitutes service upon all Filing Users in this proceeding. The docket for this proceeding indicates that all parties are Filing Users.
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U.S. Court of Appeal, Third Circuit
21400 U.S. Courthouse
601 Market Street
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6. I am a member of the bar of this Court.

DATE: March 11, 2016 *__/s/ Mark S. Hegedus__*
Mark S. Hegedus