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

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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

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 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 a5(o e)Aa33i6.8( )0h33k a5(m)210 T

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

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

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

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 thaie9ele04 Tc -0.i Td (5((e)3.6l[(t)8.5j5(c)3.r)12..a)12.1(lde)12.o.5(c)3(he)12.5

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

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 d [5(e)3.6( )8.6(o1.07) 0.004 Tc -0.ocpe

… 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-

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 provid0 Tc 0 Tw (-)Tj 0.004 Tc Tj 0.004 Tc -8(he)-4.12.1

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

"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 DoJe

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. 62-17.n.3(m)9.8(e)0.6(n)-38.4(i)8.5T itve.

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

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

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

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]

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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

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

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