Nos. 15-1184, 15-1185, 15-1186, 15-1187, 15-1274, 15-1323, 15-1342

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE EFFEXOR XR ANTITRUST LITIGATION

On Appeal from the United States District Court
for the District of New Jersey
Lead Case No. 3:11-cv-05479-PGS-LHG

BRIEF FOR AMICUS CURIAE FEDERAL TRADE COMMISSION SUPPORTING PLAINTIFFS-APPELLANTS

DEBORAH L. FEINSTEIN
Director

MARKUS H. MEIER
Acting Deputy Director

BRADLEY S. ALBERT
Deputy Assistant Director

ELIZABETH R. HILDER
JAMIE R. TOWEY
Attorneys

BUREAU OF COMPETITION
FEDERAL TRADE COMMISSION

JONATHAN E. NUECHTERLEIN
General Counsel

JOEL MARCUS
Director of Litigation

MICHELE ARINGTON
Assistant General Counsel

OFFICE OF GENERAL COUNSEL
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-3157

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INTRODUCTION

The Supreme Court held in 2013 that a brand-name drug manufacturer's "reverse payment" to a generic competitor to settle patent litigation can violate the antitrust laws. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). And this Court held earlier this year that such antitrust liability can arise not only from cash payments, but also from non-cash consideration such as the brand-name company's promise not to launch an "authorized generic" version of its drug. *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (2015). This case involves just such a promise. The district court nevertheless held that the complaint failed to state an antitrust claim, in part because the parties submitted their settlement proposal to the FTC and the FTC declined to file an objection in the underlying patent suit.[1]

That was error. Neither the submission of a patent litigation settlement to the FTC nor the absence of subsequent FTC action has antitrust significance, whether the submission is made pursuant to an agency order, a statutory requirement, a court order, or voluntarily. If the district court's ruling to the contrary were correct, resource limitations or other factors affecting agency enforcement discretion could perversely immunize anticompetitive agreements from antitrust scrutiny. Indeed, the FTC reviews almost 200 pharmaceutical

[1] Memorandum Opinion ("Op.") at 42-43, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D.N.J. Oct. 6, 2014), ECF No. 353.

agreement filings annually, and it cannot possibly identify and investigate all settlements that merit further inquiry on the timeline of private-party litigation. This Court should reject reliance on FTC inaction as a basis for insulating pharmaceutical manufacturers from antitrust liability.[2]

INTERESTS OF THE FEDERAL TRADE COMMISSION

The Federal Trade Commission is an independent agency charged with promoting a competitive marketplace and protecting consumer interests. *See* 15 U.S.C. § 41 *et seq*. As exemplified by the *Actavis* litigation, the Commission also exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry. For more than a decade, the Commission has used its law-enforcement authority to challenge patent settlements of the type at issue here.[3] And since January 2004, it has reviewed and reported on drug-patent settlements, which drug companies are now required to file with the Commission.[4]

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[2] This brief addresses only the district court's erroneous analysis of that issue. Our silence on the remaining issues is not an endorsement of any alternative basis for the district court's ruling.

[3] *See, e.g.*, *Actavis*, 133 S. Ct. 2223; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (overruled in relevant part in *Actavis*); Plaintiff Federal Trade Commission's First Amended Complaint for Injunctive Relief, *FTC v. Cephalon, Inc.*, No. 2:08-cv-02141 (E.D. Pa. Aug. 12, 2009), ECF No. 40.

[4] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2461-64 (codified at 21 U.S.C. § 355 note).

The Commission has submitted amicus briefs in a number of proceedings concerning the legality of reverse-payment agreements,[5] including a brief in the district court proceedings below. Pursuant to Fed. R. App. P. 29(a), the Commission respectfully submits this brief.

STATEMENT OF THE CASE

1. Submission of Pharmaceutical Patent Settlements to the FTC

Reverse-payment settlements arise in the context of the unique regulatory framework established under the Hatch-Waxman Act. *See generally King Drug*, 791 F.3d at 394-96. As the Supreme Court held in 2013, these settlements can raise significant anticompetitive concerns. *See Actavis*, 133 S. Ct. 2223; *see also King Drug*, 791 F.3d 388. And for more than a dozen years before *Actavis* was decided, the FTC investigated and challenged reverse-payment settlements with the twin goals of obtaining relief for consumers and deterring future anticompetitive conduct.

In 2002, the FTC partially resolved its first reverse-payment settlement challenge by entering into a consent order with defendant-appellee Wyeth (then called American Home Products).[6] At that time, pharmaceutical companies were

[5] *E.g.*, Brief of the Federal Trade Commission as Amicus Curiae in Support of Plaintiffs-Appellants, *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, No. 14-1243 (3d Cir. Apr. 28, 2014).

[6] Decision and Order, *In re Schering-Plough Corp.,Upsher-Smith Labs., Inc., & Am. Home Prods. Corp*., D. 9297 (FTC Apr. 2, 2002) ("Consent Order"),

not yet required to submit their patent settlements to the federal antitrust agencies, which made it difficult for the FTC to learn of potentially anticompetitive deals. The 2002 consent order required Wyeth to submit for FTC review certain prospective settlement agreements resolving pharmaceutical patent litigation. If Wyeth submitted an agreement to the FTC with at least 30 days' notice, the FTC did not raise an objection, and Wyeth obtained a stipulated permanent injunction, then Wyeth could enter the settlement without violating the consent order. *See* Consent Order, ¶ II. Of course, the settlement could still be unlawful under substantive antitrust law even if Wyeth complied with its procedural obligations under the consent order.

About the same time as the Wyeth consent order, Congress became 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). In 2003, Congress amended the law to require parties to file their

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https://www.ftc.gov/sites/default/files/documents/cases/2002/04/scheringplough_do.htm (cited at Op. 20 n.12). The FTC's administrative complaint alleged that, in exchange for substantial cash payments, American Home Products had unlawfully agreed with Schering-Plough Corporation to abandon a patent challenge and refrain from selling its generic version of Schering's drug for several years. *See* Complaint, *In re Schering-Plough Corp.,Upsher-Smith Labs, Inc., & Am. Home Prods. Corp.*, D. 9297 (FTC Mar. 30, 2001), https://www.ftc.gov/sites/default/files/documents/cases/2001/04/scheringpart3cmp.pdf.

pharmaceutical patent litigation settlements (and any related agreements) with the FTC and the Department of Justice. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2461-64 (codified at 21 U.S.C. § 355 note). The MMA solved the government's previous information deficit and facilitated law enforcement by providing access to all reverse-payment deals. But Congress placed no duty on the FTC or the Department of Justice to take action on a submitted settlement proposal. To the contrary, the MMA provides that "any failure of the [agencies] 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.

In March 2005, the Eleventh Circuit held that reverse payments do not trigger antitrust scrutiny unless they restrained competition beyond the "scope of the patent"—*i.e*., unless the generic agreed to stay out of the market after the patent had expired or the patent was obtained by fraud. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). This scope-of-the-patent test endured in the lower courts for eight years and, until it was rejected in *Actavis*, virtually immunized reverse-payment agreements from antitrust challenge.

After the Eleventh Circuit's ruling, Wyeth and Teva reached the settlement agreement at issue here. In accordance with the 2002 FTC consent order, Wyeth

notified the court hearing the patent case of the order's requirements. The court issued a scheduling order that set forth deadlines for the parties' submission of their agreements to the FTC and for the FTC's filing of objections to the agreements. *See* Op. 20. In response, FTC staff issued a letter to Wyeth stating that, given the agency's understanding that Wyeth and Teva did not intend "to independently raise with the Court the competitive implications of their proposed settlement agreement,"[7] it had decided not to object to the agreement at that time. *See* Op. 20-21 (quoting FTC 2005 staff letter to Wyeth's counsel). Just as Congress had provided in the MMA context, the FTC cautioned that its inaction should not be "construed as a determination that the proposed settlement agreement does not violate Section 5 of the FTC Act."[8] Op. 21 (quoting FTC staff letter).

2. The Current Litigation and the Decision Below

Plaintiffs-appellants are direct purchasers of Wyeth's product Effexor XR,

[7] In some instances, drug companies settling patent litigation have asked the court to enter stipulated findings that their settlement agreement is procompetitive, in an effort to shield the agreement from later antitrust scrutiny. *See*, *e.g.*, Stipulation and Order of Dismissal at ¶ 6, *Smithkline Beecham Corp. v. Teva Pharm. USA Inc.*, No. 2:02-cv-3779 (D.N.J. Apr. 6, 2005), ECF No. 89 ("As a result of the settlement there will be early procompetitive generic competition….").

[8] Section 5 prohibits "[u]nfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a). *See generally FTC v. Cement Institute*, 333 U.S. 683, 689-93 (1948) (Sherman Act violations redressed as violations of Section 5).

an extended release antidepressant.[9] They allege that, to induce Teva to abandon its patent challenge and refrain from selling generic Effexor XR for two years, Wyeth promised not to market an authorized generic version of Effexor XR during the 180-day period in which (under the Hatch-Waxman Act) Teva would be the exclusive generic manufacturer of the drug.[10] Plaintiffs allege that this agreement is a reverse-payment settlement that violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2. Wyeth and Teva filed motions to dismiss. The FTC submitted an amicus brief in August 2013 in connection with the district court's consideration of those motions.[11] As that brief explained, and as this Court later held in *King Drug*, a brand-name manufacturer's promise not to launch an authorized generic during the first generic applicant's exclusivity period can play the same unlawful role as the reverse payments at issue in *Actavis*.[12]

In October 2014, the district court dismissed plaintiffs' reverse-payment claims. It agreed in principle that reverse payments can take the form of non-cash consideration, such as an agreement not to compete with an authorized generic.

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[9] For simplicity's sake, this brief addresses the claims of the direct purchaser class plaintiffs.

[10] *See* Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint and Jury Demand at ¶¶ 270, 276-77, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D.N.J. Oct. 23, 2013), ECF No. 287.

[11] Federal Trade Commission Brief as Amicus Curiae, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013), ECF No. 236-2.

[12] *See id*. at 10-13; *King Drug*, 791 F.3d at 403-10.

But the court held that the plaintiffs had not stated a cognizable reverse-payment claim under *Actavis* because they had "fail[ed] to provide appropriate evidence for the Court to determine the value of the payment." Op. 40.

The district court then turned to the issues addressed in this brief. *See supra* note 2. It first held that, because Wyeth had submitted the proposed settlement to the FTC in 2005, the settlement could not constitute an "unexplained" payment subject to scrutiny under *Actavis*. Op. 42; *see id*. at 31 (citing *Actavis*'s reference to an "unexplained large reverse payment," 133 S. Ct. at 2236). The court reasoned that, under *Actavis*, "a justification [for the payment] can be seen in the intent of the parties in settling." Op. 42. And it found that "any alleged antitrust intent" here was "negated" by "the parties' willingness to submit those agreement[s] for review" by the FTC. *Id*. The court did not explain how actions required by the FTC's 2002 consent order—notice to the FTC and an opportunity for the FTC to file an objection with the patent court (*see id*. at 20 n.12)—could demonstrate Wyeth and Teva's intent in agreeing to the alleged reverse payment, let alone shield an allegedly anticompetitive deal from antitrust scrutiny.

The court further relied heavily on the FTC's decision not to object. The court faulted the FTC for declining to oppose the settlement in the patent litigation while reserving its right to take "such further action as the public interest may require." *Id*. at 21 (quoting FTC 2005 staff letter to Wyeth's counsel). "When a

governmental agency receives an invitation from the Court to intercede in a matter *by way of an Order*," the court stated, "that agency should respond appropriately, not simply reserve that right for the future." *Id*. at 43 (emphasis in original). In the court's view, this "lackluster response," given "the comprehensive review suggested by the judiciary," was "sufficient justification that the agreement between Wyeth and Teva did not constitute an unexplained payment." *Id*.

ARGUMENT

This brief addresses two related errors in the district court's opinion. First, the court mistakenly relied on the parties' advance submission of their settlement agreement to the FTC as evidence of a lack of intent to violate the antitrust laws. Second, the court erroneously regarded the agency's decision not to object at that time as a basis for insulating the settlement agreement from antitrust review. Both errors reflect a serious misunderstanding of controlling law.

I. WYETH'S COMPLIANCE WITH THE FTC CONSENT ORDER CANNOT JUSTIFY AN ALLEGED REVERSE PAYMENT.

As this Court has recognized, a brand-name drug manufacturer's promise not to market an authorized generic "transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." *King Drug*, 791 F.3d at 405. Once an antitrust plaintiff shows such a large transfer, "the burden then shifts to the defendant to show 'that

legitimate justifications are present, thereby explaining the presence of the challenged term.'" *Id*. at 412 (quoting *Actavis*, 133 S. Ct. at 2236).

Contrary to the district court's ruling, Wyeth and Teva's compliance with the notice requirements of the FTC's 2002 consent order cannot negate any element of antitrust liability. Although the court found that this submission "negated" "any alleged antitrust intent," Op. 42, a party's "good intention" cannot "save an otherwise objectionable [restraint of trade]." *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918). The rule-of-reason inquiry "is confined to a consideration of impact on competitive conditions," *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 690 (1978), and "good motives will not validate an otherwise anticompetitive practice," *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 101 n.23 (1984).

Actavis affirms these fundamental principles. The Court there held that the justification proffered by the defendants must "explain[] the presence of the challenged [reverse payment] term." 133 S. Ct. at 2236. It identified two justifications for reverse payments—"litigation expenses saved through the settlement" and "compensation for other services that the generic has promised to perform"—and observed that "there may be others." *Id*. Both of the cited justifications explain the payment and bear directly on the competitive effects of the conduct. Both demonstrate that the parties are not agreeing to maintain and

share patent-generated monopoly profits by eliminating the risk of competition. *See id.* at 2236-37.

In contrast, Wyeth's compliance with the 2002 consent order reveals nothing about the likely competitive effects of this agreement. It does not "explain[] the presence of the challenged [reverse payment] term." 133 S. Ct. 2236. Nor does it demonstrate that Wyeth is not sharing monopoly profits with a potential rival. In short, Wyeth's compliance with the consent order cannot serve as a legitimate justification for the alleged reverse payment.

II. THE FTC'S INACTION ON A FILED SETTLEMENT AGREEMENT HAS NO RELEVANCE TO THE ANTITRUST ANALYSIS.

The district court also erred in reading antitrust significance into the FTC's decision not to submit objections under the consent order. It is well established that government *inaction* does not indicate agency *approval*. *See, e.g.*, *Altria Group, Inc. v. Good*, 555 U.S. 70, 89-90 (2008). Indeed, Congress reaffirmed that basic principle when it enacted the MMA in 2003, making 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. 2463. Here, the FTC's 2002 consent order against Wyeth likewise created no immunity from antitrust law for agreements falling under its 30-day advance review provisions. *See supra* pp. 3-5. Whether review occurs before or after an agreement is executed, lack of action by the FTC does not serve

to validate the agreement or insulate it from the same antitrust principles applicable to all other agreements.

It is for good reason that courts impute no legal significance to agency inaction. An agency decision whether to act in a particular matter or at a particular time "often involves a complicated balancing" of factors: the agency must "assess whether a violation has occurred," "whether agency resources are best spent" on that matter, whether that particular action "best fits the agency's overall policies, and indeed whether the agency has enough resources to undertake the action at all." *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 and "to allocate its available funds and personnel in such a way as to execute its policy efficiently and economically." *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).

The decision below subverted these principles. In effect, the district court took a notice mechanism designed to give the FTC information and flexibility in its review of Wyeth's compliance and turned it into an escape hatch for defendants to evade antitrust scrutiny. That decision is particularly indefensible given the FTC's express statement in its response to Wyeth that its inaction should not be viewed as a determination that the settlement passed antitrust muster. *See* Op. 21 (quoting

FTC's 2005 letter to Wyeth's counsel). In short, the court erred when it treated the FTC's response as justification for potentially anticompetitive behavior under *Actavis*.

CONCLUSION

The Court should reverse the district court's holding that Wyeth's compliance with the FTC consent order, and the FTC's subsequent inaction, established that the challenged reverse payment was justified.

Respectfully submitted,

DEBORAH L. FEINSTEIN
Director

MARKUS H. MEIER
Assistant Director

BRADLEY S. ALBERT
Deputy Assistant Director

ELIZABETH R. HILDER
JAMIE R. TOWEY
Attorneys

BUREAU OF COMPETITION
FEDERAL TRADE COMMISSION

JONATHAN E. NUECHTERLEIN
General Counsel
JOEL MARCUS
Director of Litigation

s/ Michele Arington
MICHELE ARINGTON
Assistant General Counsel

OFFICE OF GENERAL COUNSEL
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-3157

November 17, 2015

COMBINED CERTIFICATIONS

1. This brief complies with the type-volume limitation set forth in Fed. R. App. 32 (a)(7)(B), in that it contains 3,049 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

2. I filed the electronic PDF version of this brief with the Court via the CM/ECF system. The docket for this proceeding indicates that all participants in the case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

3. The text of the electronic PDF version of this brief is identical to the text of the paper copies being sent to this Court.

4. I ran a virus check on the electronic version of this brief using used Symantec Endpoint Protection version 12.1.4112.4156, and it detected no virus.

5. Because this brief is filed on behalf of an administrative agency of the United States, there is no bar membership requirement.

November 17, 2015

s/ Michele Arington
MICHELE ARINGTON