IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 14-1243

In re Lamictal Direct Purchaser Antitrust Litigation

King Drug Co. of Florence, Inc., et al.,
Plaintiffs-Appellants,

v.

SmithKlineBeecham Corp., et al.,
Defendants-Appellees.

On Appeal from the United States District Court
For the District of New Jersey (No. 2:12-cv-995-WHW-CLW)

BRIEF OF FEDERAL TRADE COMMMISSION AS AMICUS CURAIE IN SUPPORT OF PLAINTIFFS-APPELLANTS

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INTRODUCTION

In *FTC v. Actavis*, 133 S. Ct. 2223 (2013), the Supreme Court reaffirmed that traditional antitrust principles apply to patent settlements and that patent law confers no broad immunity on parties to such agreements. Applying that principle, the Court held that a brand-name drug manufacturer's payment in patent litigation to a potential generic entrant can violate the antitrust laws under the rule of reason. The Court contrasted such "reverse payment" cases with certain other patent settlements, including those in which the parties simply specify a date on which generic entry will be permitted. As the Court recognized, agreements in the latter category are normally unproblematic because they presumably reflect only the parties' risk-adjusted views of likely litigation outcomes. *Id.* at 2237. But antitrust concerns do arise where a branded-drug company agrees to make a reverse payment to compensate a generic company for staying out of the market for some period, thereby eliminating the risk of competition and preserving—while sharing—the branded-drug company's monopoly profits.

Originally, reverse payments often took the form of outright cash transfers. Today, after years of antitrust scrutiny, a branded-drug company may sometimes induce a generic company to stay out of the market by offering it payments in kind rather than in cash. This case exemplifies that phenomenon.

The reverse payment alleged here took the form of a valuable contractual commitment. Teva Pharmaceuticals initially challenged a patent that purportedly covered the anti-epileptic drug Lamictal and sought to introduce a cheaper, generic version. Congress enacted the Hatch-Waxman Amendments of 1984 precisely to spark challenges of this sort. Such challenges, when successful, greatly reduce drug prices to the benefit of consumers. But Teva abandoned its challenge in favor of a settlement agreement with GlaxoSmithKline, LLC (GSK), the manufacturer of brand-name Lamictal.

That agreement freed GSK from the uncertainties of a patent challenge and guaranteed that it would enjoy several more years of monopoly profits. GSK, in turn, agreed that, when Teva *did* finally introduce generic Lamictal tablets, GSK would refrain from introducing its own authorized generic (AG) product—*i.e.*, the brand-name drug, but marketed as a generic product. That "No-AG commitment" allowed Teva to capture all generic sales for six months and thus earn supracompetitive profits of its own. Thus, according to the complaint, the agreement denied consumers the opportunity to purchase generic Lamictal for several years and then, when a generic version finally became available, ensured that consumers would pay more for it than if the two companies had offered competing generic products. As alleged, the arrangement was a win-win for the parties, but a loss for consumers.

The district court nonetheless dismissed this case. It distinguished *Actavis* on the ground that the branded-drug company there had compensated the generic company in cash to induce it to stay out of the market for a defined period, whereas the branded-drug company here extended compensation in the form of a valuable agreement not to compete. The *Actavis* decision does not distinguish among the many forms of compensation that can support a potentially problematic reverse-payment settlement. If accepted, the district court's narrow reading of *Actavis* would undermine the Supreme Court's decision in that case and encourage parties to structure potentially anticompetitive reverse-payment settlements simply by avoiding the use of cash. This Court should reverse.

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*. It has substantial experience concerning the balance between antitrust and intellectual property laws.[1] The Commission also exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry.

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[1] *See, e.g.*, Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) (http://www.ftc.gov/reports/antitrust-enforcement-intellectual-property-rights-promoting-innovation-competition-report); U.S. Department of Justice & Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights:*

Of particular relevance here, the Commission has used its law enforcement authority to challenge patent settlements under the Hatch-Waxman Amendments,[2] which Congress enacted in 1984 to encourage greater generic competition for prescription drugs.[3] In 2002, the Commission also conducted a comprehensive study of generic drug entry,[4] and since January 2004, it has reviewed drug-patent settlements that drug companies are now required to file,[5] reporting those results annually. In 2011, the Commission published the results of a comprehensive

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Promoting Innovation and Competition (2007) (http://www.ftc.gov/reports/innovation/P040101PromotingInnovationand Competitionrpt0704.pdf); Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (www.ftc.gov/os/2003/10/innovationrpt.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995) (http://www.justice.gov/atr/public/guidelines/0558.pdf)

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

[3] *See, e.g., FTC v. Actavis*, 133 S. Ct. 2223 (2013); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. filed Aug. 12, 2009).

[4] *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study) (*Generic Drug Study*).

[5] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, § 1112 (codified at 21 U.S.C. § 355 note).

empirical study, requested by Congress, of the competitive effects of authorized generics.[6]

The Commission has submitted briefs as amicus curiae in a number of proceedings concerning the legality of reverse-payment agreements.[7] Courts, including the Supreme Court and this Court, have relied on FTC studies when resolving legal and policy issues.[8] Pursuant to Fed. R. App. P. 29(a), the Commission respectfully submits this brief.

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[6] Federal Trade Commission *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf (*AG Report*) (which analyzed data from industry and commercial sources, as well as business documents from more than 100 brand and generic pharmaceutical companies).

[7] *See, e.g., In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-2079, Brief of the Federal Trade Commission as Amicus Curiae Supporting Appellants and Urging Reversal (3d Cir. May 18, 2011).

[8] *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (FTC study on generic pharmaceuticals); *Granholm v. Heald*, 544 U.S. 460, 466–68, 490–92 (2005) (FTC study of Internet wine sales); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765-66 n.20 (1976) (FTC study concerning drug price advertising restrictions); *In re: K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (FTC report describing patent litigation settlements under the Hatch-Waxman Act), *cert. granted, vacated and remanded sub nom. Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013).

STATEMENT OF THE CASE

1. Pharmaceutical Patents, Generic Entry and the Hatch-Waxman Amendments

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, 21 U.S.C. § 301 *et seq.*, the manufacturer of a new drug must obtain approval from the Food and Drug Administration (FDA) of a new drug application (NDA) before marketing the drug. 21 U.S.C. § 355(b).[9] A drug approved under the NDA process is often referred to as a "brand-name" drug. *See generally Caraco*, 132 S. Ct. at 1675-76.

In 1984, Congress enacted the Hatch-Waxman Amendments, which established how the manufacturer of a "generic" version of a previously introduced brand-name drug may obtain approval of its product from the FDA using an Abbreviated New Drug Application (ANDA) allowing it more quickly to enter the market. To encourage generic entry as soon as warranted, the Amendments provide certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of the patent(s) claimed to cover the counterpart brand-name drug. In such cases, the generic applicant must certify that the patent in question is invalid or not infringed by the generic product (or both).

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[9] All references in this brief to Title 21 are to the 2000 version of the United States Code. As used in this brief, "drug" refers to a drug, as defined in 21 U.S.C. § 321(g)(1), that is regulated by the FDA under 21 U.S.C. § 355.

This is known as a "paragraph-IV certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see generally Caraco*, 132 S. Ct. at 1676-77.

The Hatch-Waxman Amendments encourage (though they do not require) the brand-name manufacturer to respond to a paragraph-IV certification by promptly suing the generic applicant for patent infringement. Such a suit triggers an automatic stay of FDA approval of the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). On the generic side, the Hatch-Waxman Amendments reward the first-filer of an ANDA containing a paragraph-IV certification with eligibility to be the exclusive generic provider of the drug for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). That exclusivity protects the first-filer from price competition from other ANDA filers during the period of exclusivity, and it gives that manufacturer a head start in reaching commercial arrangements with large purchasers. According to the generic pharmaceutical industry's leading trade association, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period."[10] Significantly, however, the 180-day marketing exclusivity does not preclude the *branded-drug company* from marketing an AG, which is sold under the brand's NDA as a generic without the

[10] Comments of Generic Pharm. Ass'n (GPhA) to FTC on Authorized Generic Drug Study 2 (Jun. 27, 2006), http://www.ftc.gov/policy/public-comments/2006/06/27/comment-6.

trademark or brand name. *See Teva Pharm. Indus. v. Crawford*, 410 F.3d. 51, 54 (D.C. Cir. 2005).

2. The Economics of Generic Entry and Reverse-Payment Agreements

Of the approximately $329 billion domestic drug market in 2013, brand-name drugs accounted for 14% of total prescriptions for drugs and biologics (which include products such as vaccines) but 71% of total spending.[11] That disparity reflects, *inter alia*, the monopoly reward that sellers are able to reap from patented drug products.

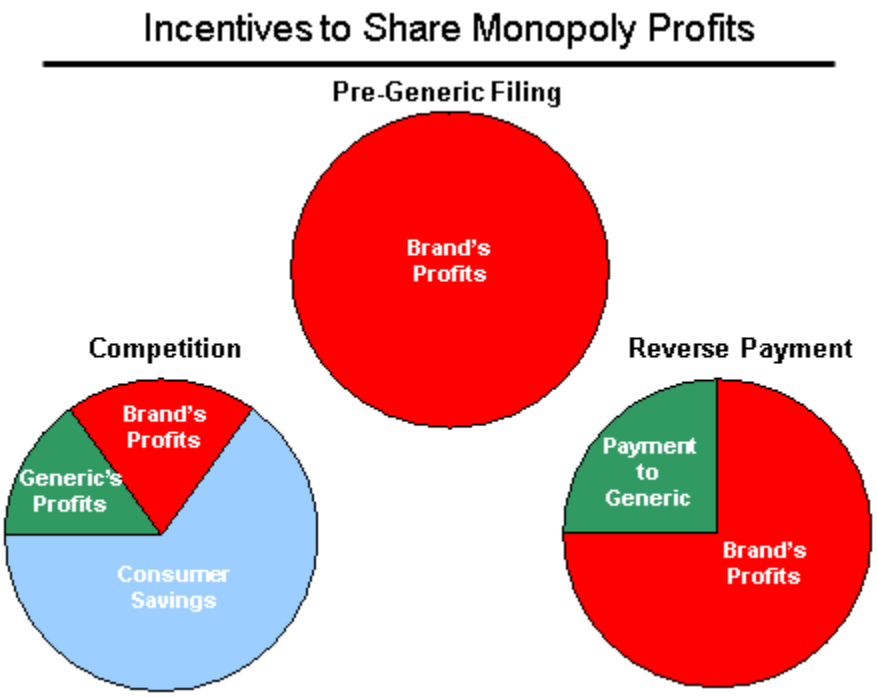
When the first generic version of a given drug comes on the market, it is priced, on average, nearly 15% lower than the brand-name drug. *See AG Report* at ii-iii. Prices fall further when additional generic competitors enter so that, on average, generic prices end up at an 85% discount compared to what the brand-name manufacturer was charging. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Eventually, the brand-

[11] IMS Inst. for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, at 30, 40 (Apr. 2014), http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=c01665b5b0845410VgnVCM10000076192ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default (requires free registration to download).

name drug loses on average about 90 percent of its market share (by unit sales) to its generic competitors. *Ibid*. Market competition from generic pharmaceuticals thus saves consumers many billions of dollars annually. *See* U.S. Gov't Accountability Off., *Report No. GAO-12-371R, Savings from Generic Drug Use* 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf (discussing studies).

Given the significant disparity between monopoly and competitive drug prices, a brand-name manufacturer has strong incentives to induce its would-be generic competitor to forgo competition, and it can offer the generic competitor strong incentives to cooperate. As the diagram below illustrates, while the generic manufacturer will profit if it prevails in paragraph-IV litigation and enters the market, it will gain much less than the brand-name manufacturer stands to lose, and competition shrinks the total profits the two companies will earn in the aggregate. As a result, both the brand-name and generic manufacturers may benefit (at the expense of consumers) if the brand-name manufacturer agrees to share its monopoly profits in exchange for the generic manufacturer's agreement to defer its own entry into the market and thereby keep overall profits at monopoly levels. *See, e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 635-36 (2009). Indeed, such a deal may yield a net benefit to the brand-name manufacturer even if it pays its would-be generic competitors more than they would earn if they

entered the market. *Actavis*, 133 S. Ct. at 2235 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1581 (2006)).



These patent settlements can be anticompetitive when the brand-name manufacturer (the patent plaintiff) provides compensation to the generic company (the defendant) in addition to the parties' agreement on a date for generic entry. The generic presumably provides some *quid pro quo* in these circumstances, regardless of whether the brand-name company has paid the generic in cash or in kind. In the absence of another explanation, that *quid pro quo* may well take the form of the generic company's agreement to stay out of the market for some period in exchange for the branded-drug company's payment. By contrast, if the parties

agree to a date on which generic entry will be permitted and go no further, the agreement is generally unproblematic because it presumably reflects merely the parties' risk-adjusted views of the likely outcome of patent litigation.

3. The Economics of a No-AG Commitment

In the earliest reverse-payment arrangements, the branded-drug company typically compensated the generic company *in cash* for abandoning its patent challenge. After more than a dozen years of antitrust scrutiny, however, parties to such arrangements now use less obvious forms of compensation.[12] An increasingly common mechanism involves the brand-name manufacturer's agreement not to introduce an AG in competition with the generic manufacturer in exchange for the generic's agreement to forestall its own entry.[13]

Brand-name companies often introduce AGs to stem the large losses that result from the rapid shift from sales of brand-name drugs to cheaper generic products. *See AG Report* at 12-14, 26-27. As the FTC's *AG Report* describes, a

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[12] Commentators have noted that after the FTC began challenging cash-only reverse-payment agreements, pharmaceutical companies then turned to other payment arrangements. *See, e.g.*, Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L.J. 83, 98 (2009).

[13] *See* FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act* (FY 2012) at 2, http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

first-filer generic company faces two primary financial effects when it must compete against an AG during the 180-day exclusivity period. First, the AG takes a significant share of generic sales away from the first-filer. *Id.* at 57-59. Second, competition between the first-filer generic and the AG drives down generic drug prices. *Id.* at 41-48. The FTC's *AG Report* found that generic wholesale prices average 70 percent of the pre-entry brand-name drug price when the first-filer faces an AG, compared to 80 percent of the brand price when it does not. *Id.* at iii. Because of these two effects, "the presence of authorized generic competition reduces the first-filer generic's revenues [during the 180-day exclusivity period] by 40 to 52 percent, on average." *Id.*; *see also id.* at 33.[14] The financial effects of an AG on the first-filer generic are well known in the pharmaceutical industry.[15]

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[14] The report notes that the effects of an AG continue well after first-filer exclusivity expires, as "[r]evenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an [authorized generic]." *Id.* at iii.

[15] According to the trade association for the generic companies: "To GPhA's knowledge, the brands have launched an authorized generic during every 180-day generic exclusivity period since September 2003. Such products have improperly deprived generic companies of literally hundreds of millions of dollars in sales. Indeed, the first generic to challenge the Paxil® patents lost revenues of nearly $400 million on this product alone when the brand launched an authorized generic during the true generic's exclusivity period." Generic Pharmaceutical Association Letter to Senate Special Committee on Aging at 5 (Jul. 27, 2006), http://gpha.hfwebdev.com/sites/default/files/Smith%20and%20Kohl%20Letter.pdf.

Accordingly, a generic company enjoys substantial benefits from a No-AG commitment in which the branded-drug company cedes all generic sales to the first generic filer for a period of time. The FTC's study found that, with a no-AG commitment, "the first-filer's revenue will approximately double" on average, compared to what the first-filer would make if it faced AG competition. *AG Report* at vi. Given the blockbuster status of Lamictal, GSK's agreement not to launch an AG version of Lamictal tablets during Teva's exclusivity period may have increased Teva's revenues by hundreds of millions of dollars.

Teva itself acknowledged these economic realities in the 2008 annual report it filed with the Securities and Exchange Commission. According to Teva, its generic Lamictal tablet product generated "substantially increased" revenues because it did not face generic competition during the exclusivity period. *See* Teva Pharm. Indus. Ltd., Annual Report (Form 20-F, at 5 (Feb. 27, 2009), http://media.corporate-ir.net/media_files/IROL/73/73925/fr/2008/2008-ar-20f.pdf).

As the FTC's *AG Report* observed, the industry understands that a No-AG commitment can be a win-win for the brand and generic. For example, one branded-drug company's analysis showed that such an agreement could maximize "the combined net present value of both companies' products," resulting in their sharing of supracompetitive profits. *AG Report* at 142 (emphasis added). The

potential victims in such arrangements are consumers, who end up paying far more than they otherwise would.

4. The Supreme Court's Decision in *FTC v. Actavis* and the Current Litigation

The plaintiffs' complaint in this case alleges that GSK induced Teva to stay out of the market for a defined period by promising that, once Teva finally did enter, GSK would not compete against Teva with authorized-generic versions of Lamictal. In 2012, the district court granted GSK's and Teva's motion to dismiss that complaint. The court declined to apply this Court's analysis of reverse-payment settlements in *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (2012), by incorrectly limiting the broad principles articulated in that ruling to cases involving the payment of cash. Plaintiffs appealed to this Court, which stayed the proceeding pending the U.S. Supreme Court's ruling in *FTC v. Actavis*.

In *Actavis*, the Supreme Court held that reverse-payment patent settlements can violate the antitrust laws and should be evaluated under the rule of reason. 133 S. Ct. at 2237-38. The FTC's complaint in that case alleged that the brand-name manufacturer of the testosterone replacement drug AndroGel had agreed to pay two generic companies in exchange for their agreements to stay off the market for six years. The district court dismissed the complaint, and the Eleventh Circuit affirmed. It reasoned that the agreements were "immune from antitrust attack" if their anticompetitive effects were all within "the scope of the exclusionary

potential of the patent." *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

The Supreme Court reversed and, in the process, rejected this so-called "scope-of-the-patent" test and its resulting immunity for settlement agreements that do not exceed the exclusionary potential of the patent. 133 S. Ct. at 2230. The Court explained that its longstanding approach to assessing whether agreements between a patentee and potential competitors violate the antitrust laws considers "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 2231.

Shortly after the Supreme Court issued its decision, this Court remanded this case for further proceedings. Plaintiffs moved for reconsideration of the district court's original decision granting the motion to dismiss. The court rejected plaintiffs' motion and reaffirmed its original decision. It stated that the *Actavis* opinions "reek with discussion of payment of money" (slip op. at 13) and concluded that the principles of *Actavis* apply only where there is a "payment of money." *Id.* at 15. The district court also opined that, even if the rule of reason applied, this agreement would likely survive scrutiny. *Id.* at 18-19.

SUMMARY OF ARGUMENT

Actavis reaffirmed that patent settlements enjoy no broad antitrust immunity and are subject to traditional antitrust principles. The district court held that "*Actavis* scrutiny applies only to patent settlements that contain reverse payments" (slip op. at 11), and that, even then, "only to 'reverse payments' of money" (slip op. at 13). But *Actavis* did not establish a special rule limited to reverse-payment cases. Rather, the Supreme Court explained that its directive to consider traditional antitrust factors applies generally in cases challenging "patent-related settlement agreements" and "overly restrictive patent licensing agreements." *Id.* at 2231-34. The No-AG commitment here has all the hallmarks of the kind of settlement that the Supreme Court held is subject to antitrust scrutiny.

Under the facts alleged here, Teva obtained something that it could not have won had it prevailed in its patent litigation: GSK's promise not to compete using an AG during Teva's exclusivity period. In return, Teva agreed to drop its challenge to GSK's patent claiming Lamictal, thus preserving GSK's monopoly profits, which GSK then shared with Teva by ceding all generic sales for a period of time to Teva through a No-AG commitment.

As alleged, the No-AG commitment is thus a reverse payment that maintains "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.

The commitment "prevent[s] the risk of competition" to the branded-drug company (*id.*)—*i.e.*, by eliminating the threat of a finding of patent invalidity or noninfringement—for a defined period, ensuring GSK's monopoly prices during that period. That commitment similarly guarantees that, even after generic entry, Teva can charge higher (supracompetitive) generic prices than if GSK competed with an AG during the 180-day exclusivity period, which the complaint alleges would have occurred here. Consolidated Am. Class Action Complaint (Compl.) ¶ 118, Case 2:12-cv-00995-WHW-CLW, Dkt. 55. This arrangement is a win-win for the parties, because it enlarges their aggregate pool of supracompetitive profits in each of these two respects. But it does so at the expense of the consumers who must underwrite those profits in the form of higher drug prices.

The district court elevated form over substance when it concluded that such reverse payments trigger antitrust scrutiny only when they are made in cash rather than in kind. That rationale would perversely allow parties settling patent litigation to avoid antitrust review simply by sharing their enhanced monopoly profits in a form other than cash. But whether such sharing takes the form of gold bullion, stocks, free goods, real estate, or—as here—an additional agreement not to compete, the potential for harm to consumers is present. In any event, a settlement with a No-AG commitment can violate the antitrust laws whether it is characterized as a reverse payment (in kind rather than in cash) or instead as a

reciprocal agreement not to compete. As *Actavis* confirms, mutual non-compete agreements involving patents, including this one, are subject to rule-of-reason scrutiny. The Court should thus reverse and remand the case for a proper rule-of-reason analysis.

ARGUMENT

I. *ACTAVIS* CONFIRMS THAT PATENT SETTLEMENTS BETWEEN A PATENTEE AND ITS POTENTIAL COMPETITOR ARE SUBJECT TO TRADITIONAL ANTITRUST PRINCIPLES

In *Actavis*, the Supreme Court rejected the scope-of-the patent test and directed courts to consider traditional antitrust factors. The holding is not a special rule limited to "reverse-payment" cases. As the Court noted, it is the approach that applies generally to antitrust cases challenging "patent-related settlement agreements" and "overly restrictive patent licensing agreements." *Actavis*, 133 S. Ct. 2231-34.[16] The Court observed that the Sherman Act can impose "'strict limitations on the concerted activities in which patent owners may lawfully

[16] The federal enforcement agencies' 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* reflect this approach. *See* U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* at 7-8 (Apr. 6, l995). They discuss how antitrust analysis applies to a wide variety of restraints that may appear in patent license agreements, explaining that traditional antitrust principles take into account the distinctive characteristics of intellectual property.

engage." *Id.* at 2232 (quoting *United States v. Singer Mfg. Co.*, 374 U.S. 174, 197 (1963)).

The Supreme Court's rejection of an antitrust immunity premised on the "scope-of-the-patent" approach was unequivocal. The Court explained that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Actavis*, 133 S. Ct. at 2231. "For one thing, to refer, as the [Eleventh] Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question." *Id.*; *see also K-Dur*, 686 F.3d at 214 (presuming patent validity "assumes away the question being litigated in the underlying patent litigation"). Rather, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Actavis*, 133 S. Ct. at 2231.

Of course, as the Supreme Court observed, a patent holder *might* be able to exclude competition until patent expiration *if* the relevant patent is valid and infringed. But the Court rejected the argument "that that fact, or characterization, can immunize the agreement from antitrust attack." *Id.* at 2230. The right of a patent holder to defend its patent against infringement does not entail a right to "pay a competitor to respect its patent and quit its patent invalidity or

noninfringement claim without any antitrust scrutiny whatever." *Id.* at 2233. "It would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *Id.* (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)). Indeed, the Court observed that the removal of an uncertain risk of invalidity or non-infringement, even if small, cannot justify an otherwise unexplained large reverse payment:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.

Id. at 2236.

The district court overlooked these critical aspects of the *Actavis* decision. For example, the court repeatedly noted that the settlement agreement here permitted generic entry before patent expiration, as though that fact insulated the agreement from antitrust review. *See* slip op. at 12, 16, 18, 19. But *Actavis* involved an agreement providing for entry five years before patent expiration. *See* 133 S. Ct. at 2229. The Court nonetheless found that the agreement could violate the antitrust laws.

Similarly, the district court erred when it construed the statement in *Actavis* that patent litigants may, without risking antitrust liability, "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." Slip op. at 12 (quoting *Actavis*, 133 S. Ct. at 2237). Contrary to the district court's analysis, the *Actavis* decision does not mean that only cash-payment settlements receive antitrust scrutiny, much less that "[o]ther types of settlement are explicitly exempt" (slip op. at 12). Indeed, some of the cases that the Court discussed involved agreements allowing for entry before patent expiration and provided no cash payment to the allegedly infringing party. *Id.* at 2232-33. These agreements were nonetheless found to violate the Sherman Act because they contained other aspects that raised antitrust concerns. *See, e.g.*, *United States v. New Wrinkle*, 342 U.S. 371, 378 (1952) (finding that patent licenses granted under a settlement agreement could violate the antitrust laws if they are the means by which patent holders jointly regulate distribution and control prices). The *Actavis* Court's reliance on those precedents would make no sense if the Court had intended its ruling to apply only to a narrow range of cases in which cash is exchanged.

Thus, in the cited passage, the Supreme Court observed that competitors do not normally raise antitrust concerns if they agree on a date for generic entry but do *not* simultaneously agree that the brand-name manufacturer will compensate the generic company for staying out of the market until that date, thereby sharing

(while enlarging) their aggregate pool of monopoly profits. In such cases, this familiar settlement form generally reflects nothing more than arms-length bargaining between adverse parties based on their expectations about the likely outcome of the litigation. But a key lesson of *Actavis* is that "patent-related settlement agreements" and "overly restrictive patent licensing agreements" (133 S. Ct. at 2231-34) are generally subject to review under traditional antitrust factors, and are not automatically "exempted" from antitrust liability. The district court erred in concluding otherwise.

II. A NO-AG COMMITMENT RAISES ALL THE SAME CONCERNS THAT THE *ACTAVIS* COURT IDENTIFIED AS A BASIS FOR ANTITRUST REVIEW

The district court held that the complaint did not state a claim under *Actavis* because GSK did not pay Teva cash to refrain from market entry. Slip op. at 13-14. But a distinction between cash and non-cash payments makes no economic or legal sense. It is not the transfer of cash or the form of reverse payment that triggers antitrust concern; it is the impact of that payment on consumer welfare.

The Supreme Court has long emphasized that antitrust analysis turns on economic substance, not form.[17] The district court ignored that basic principle. If

[17] *See, e.g.*, *American Needle, Inc. v. Nat'l Football League*, 130 S. Ct. 2201, 2211 (2010) ("substance, not form, should determine whether a[n] … entity is capable of conspiring") (quoting *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S.

the district court's distinction between cash and non-cash consideration were valid, it would mean that the parties in *Actavis* itself could have avoided antitrust scrutiny altogether simply by replacing their cash payment with some non-cash consideration of equivalent value, such as bonds, museum art, or real property. And it would mean that all future parties contemplating anticompetitive reverse-payment agreements could evade the holding of *Actavis* simply by choosing some non-cash equivalent as compensation to the generic for abandoning its patent challenge and agreeing to stay out of the market until a date certain. But antitrust principles are not so easily evaded. Substituting one form of consideration for another does not protect consumers from the harms of anticompetitive agreements between competitors, nor does it alter the antitrust analysis.

In particular, "significant adverse effects on competition" can arise whenever a settlement (1) provides the generic challenger something that it could not have obtained had it won its litigation, *Actavis*, 133 S. Ct at 2231, and (2)

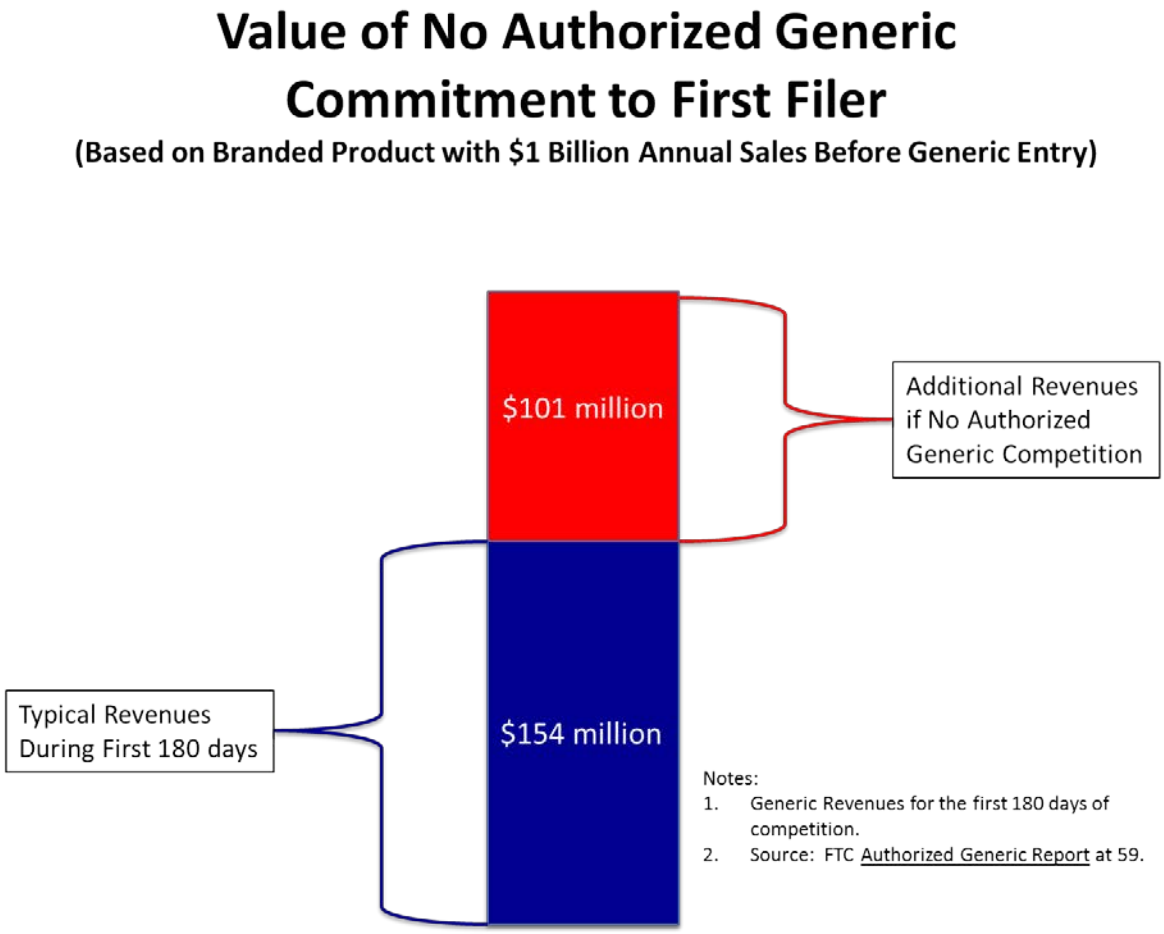
752, 773 n.21 (1984)); *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 466-67 (1992) (in assessing market power, "this Court has examined closely the economic reality of the market at issue," rather than resting on "formalistic distinctions"); *see also K-Dur*, 686 F.3d at 218 (requiring an antitrust analysis based on "economic realities" rather than labels); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) ("The Supreme Court on more than one occasion has emphasized that economic realities rather than a formalistic approach must govern review of antitrust activity."); *Weiss v. York Hosp.*, 745 F.2d 786, 815 (3d Cir. 1984) ("Antitrust policy requires the courts to seek the economic substance of an arrangement, not merely its form.").

allows the parties "to 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 facts alleged here satisfy both conditions. The agreement in this case plainly gave Teva something it could not have won in the patent litigation: the ability to introduce its generic product with a period free from competition, not only from other ANDA generics, but from any AG. Moreover, the agreement maintains supracompetitive prices in which GSK and Teva both share.

GSK, as alleged, paid for that agreement with an economically consequential No-AG commitment. Under the FDCA, a brand may, as a matter of right, introduce an AG product at any time. Typically a brand does so during the six-month exclusivity window following generic entry, thus siphoning substantial revenues from the generic company with an exclusivity period and creating price-reducing competition that benefits consumers. When the brand agrees to forgo selling an AG, however, it essentially hands revenues it would have earned through AG sales back to the first-filer generic company and creates the ability for the generic entrant to price at supracompetitive levels. In turn, a brand-name manufacturer is willing to forgo the profits it would earn with an AG only because of the monopoly profits secured by the generic's agreement to stay off the market for a period of time.

The value of such a No-AG commitment is large. Typically, eliminating an AG during the first 180 days increases a first-filer's revenue (such as Teva's in this situation) by approximately 65 to 100 percent.[18] As shown in the graph below, during the first 180 days of generic sales, a first-filer would earn (based on conservative estimates) an additional $101 million dollars on a brand-name drug with one billion dollars in annual sales, if the branded-drug company agreed not to compete with an AG. That agreement would increase the first-filer's revenue from $154 million to $255 million during the 180-day exclusivity period.

[18] The *AG Report* (at 59) found that the existence of an AG competitor reduced the first-filer's revenue by approximately 40 to 50 percent during the first 180 days.



These added revenues are indistinguishable in any legally or economically significant way from a reverse payment made in cash that the Court analyzed in *Actavis*. The first-filer generic would not have realized these revenues had it won its patent litigation, and the brand is willing to forgo them only because the generic agreed to drop its patent challenge. The mere fact that the generic company earns these additional revenues does not make them comparable to the revenues it would earn in a settlement that compromises on an entry date without payment of any kind. In a no-AG deal, the branded-drug company enables the generic to earn these

added revenues by giving up its unqualified right to market an AG product, and thereby transfers economic value to the generic as surely as if it had written a check.[19]

Moreover, characterizing a No-AG commitment as a form of "exclusive license," as the defendants in this case did below, does not change the analysis. Most exclusive licenses raise no antitrust concerns because they promote competition, such as by combining complementary assets. U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, Section 3.1, at 17 (Apr. 6, 1995) ("While intellectual property licensing arrangements are typically welfare-enhancing and procompetitive, antitrust concerns may nonetheless arise."). Here, however, any "exclusive license" would simply take the form of a No-AG commitment,[20] which

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[19] Indeed, because a No-AG commitment can approximately double the revenues generated by the first-filer, the value might be more than the first-filer could have earned by prevailing in the patent litigation. *See AG Report* at vi.

[20] Exclusive licenses encompass a variety of types of arrangements and arise in a variety of contexts. Teva has wrongly claimed elsewhere that the FTC took the position in *Actavis* that an exclusive license can never be a reverse payment. *See* Defendants' Reply Brief in Support of Motion to Dismiss (Feb. 14, 2014) at 10, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-5479 (D. N.J.). But whether a particular exclusive license amounts to a reverse payment must be evaluated on its facts. The FTC has consistently characterized No-AG commitments to first-filers as payments, regardless of whether the commitment took the form of an exclusive license. *See, e.g., AG Report* at 144-45.

does *not* promote competition and instead merely enlarges the pool of shared supracompetitive profits.[21]

III. RECIPROCAL AGREEMENTS NOT TO COMPETE CAN CAUSE ANTICOMPETITIVE HARM AND MAY VIOLATE THE ANTITRUST LAWS

As discussed, No-AG agreements are *at least* as worthy of antitrust scrutiny as agreements in which branded companies pay generic companies cash to stay out of the market. If anything, No-AG agreements raise even further antitrust concerns because they embody a *second, additional* agreement not to compete. In particular, No-AG commitments harm consumers first by inducing the generic to abandon its patent challenge, and then by producing inflated generic prices *even after* generic entry because of the absence of competition from an AG. See *AG Report* at ii-iii.[22]

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[21] More generally, exclusive licensing agreements are not immune from antitrust scrutiny. As stated in the leading antitrust treatise, which is cited several times by the Supreme Court in *Actavis*: "Assuming the patent is valid, the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny." 12 Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 330 (3d ed. 2012) (footnotes omitted); *see also Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931) (applying rule-of-reason antitrust scrutiny to cross-licensing agreements); *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1372 (3d Cir. 1996) (subjecting exclusive licenses to rule of reason analysis). "Though the grant of an exclusive license is not *per se* a violation of the antitrust laws, it may be an instrument by which an unlawful restraint of trade or a monopoly is created." *Benger Labs. Ltd. v. R.K. Laros Co.*, 209 F. Supp. 639, 648 (E.D. Pa. 1962).

[22] That second phase of consumer harm may occur all in the span of six months, as the district court observed, slip op. at 18, but the relative brevity of that period is

Such agreements can be viewed not only as reverse payments, but also as reciprocal agreements not to compete, which are independently subject to rule-of-reason scrutiny in this setting. *See Actavis*, 133 S. Ct. at 2237; *see also Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931) (analyzing terms of patent settlement agreement under the rule of reason); *Moraine Products v. ICI America, Inc.*, 538 F.2d 134, 144-46 (7th Cir. 1976) (exclusive patent license subject to rule-of-reason analysis). Indeed, in *Actavis*, the Supreme Court cited its most recent precedent involving reciprocal agreements not to compete, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990), in framing the key question about reverse-payment agreements—"whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws." *See Actavis*, 133 S. Ct. at 2227.

In this case, the plaintiffs have alleged that GSK and Teva entered into reciprocal agreements not to compete. At the time of the settlement, GSK faced a risk of competition from Teva, and Teva faced a risk of authorized-generic competition during its exclusivity period. Under the settlement, Teva agreed not to compete against GSK for Lamictal tablets from February 2005 to July 2008, and GSK agreed not to market a generic form of the Lamictal tablet in competition

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no basis for assuming, as the court did (*id.*), that such harm is insubstantial. To the contrary, it can account for tens of millions of dollars of consumer losses, as discussed above.

with Teva from July 2008 to January 2009. Compl. ¶ 93 (Teva agreed not to market generic until July 2008); ¶ 86 (GSK agreed not to launch AG until January 2009). When, as the complaint alleges here, each of those agreements allows the remaining competitor to charge supracompetitive prices, such agreements can violate the antitrust laws. As alleged, these are simply agreements by potential competitors to stay out of each other's backyard.[23]

[23] It is not necessary to find that the two companies previously competed in a market to find such agreement not to compete unlawful, because "prevent[ing] the risk of competition … constitutes the relevant anticompetitive harm." *Actavis*, 133 S. Ct. at 2236.

CONCLUSION

The Court should reverse the district court's decision and remand the case for further proceedings consistent with the Court's decision.

Respectfully submitted,

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April 28, 2014

COMBINED CERTIFICATES – CASE 14-1243
BRIEF OF FEDERAL TRADE COMMMISSION AS AMICUS CURAIE
IN SUPPORT OF PLAINTIFFS-APPELLANTS

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. Civ. P. 32(a)(7)(B). It has 6,600 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.
3. The electronic version of this brief is in PDF and was scanned using Symantec Endpoint Protection Version 12.1.1000.157 with virus definitions updated April 28, 2014. No viruses were detected.
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.
5. I have caused to be sent to the Court seven hard copies of this brief via FedEx Next Day Delivery to:

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6. I am a member of the bar of this Court.

DATE: April 28, 2014 *_/s/ Mark S. Hegedus_*
Mark S. Hegedus