IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

NOS. 14-2071 and 15-1250
(consolidated)

American Sales Co., et al.,
Plaintiffs-Appellants,

v.

Warner-Chilcott Co., LLC, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
For the District of Rhode Island (No. 1:13-md-02472-S-PAS)

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

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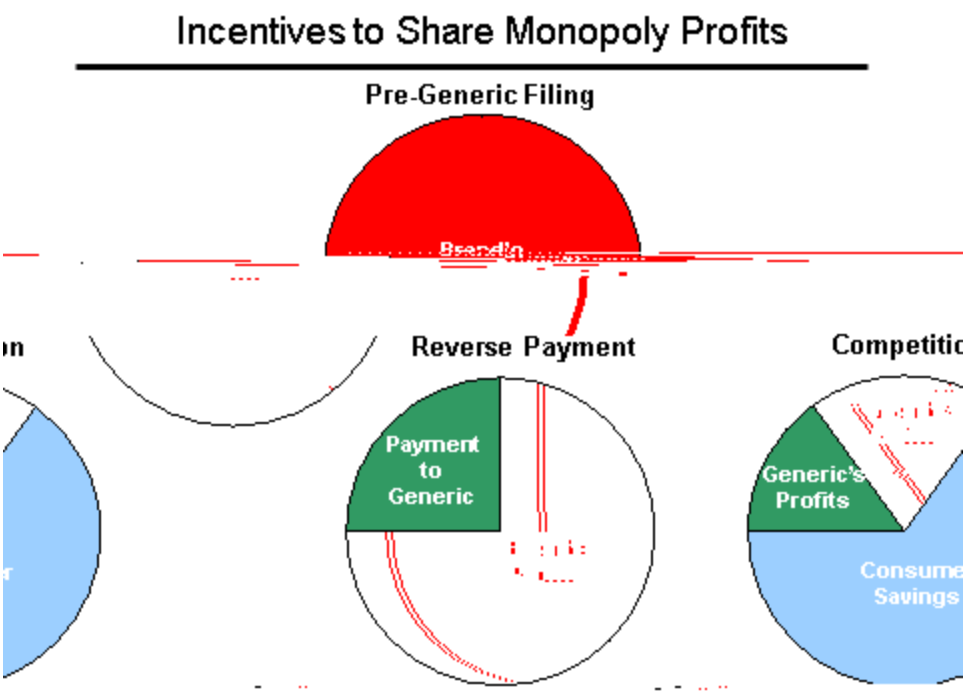
Generic versions of brand

ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). To encourage generic companies to avail themselves of this process, the Hatch-Waxman Amendments entitle the first filer of an ANDA containing a paragraph-IV certification to a 180-day period of qualified market exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). That exclusivity protects the first filer from price competition from ot

company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf. Eventually, the brand-name drug loses on average about 90 percent of its market share (by unit sales) to its generic competitors. *Id*. Market competition from generic pharmaceuticals thus saves consumers 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 both strong incentives to keep its would-be generic competitor on the sidelines and the ability to offer the generic competitor powerful inducements 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:



In other words, competition shrinks the total profits the two companies will earn in the aggregate. As a result, both the brand-name and generic manufacturers 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 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 have earned if they had 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)).

Competitive concerns do not ordinarily arise if a brand-name manufacturer and a generic competitor settle a paragraph-IV patent lawsuit simply by agreeing to

No. 1:13-md-02472-S-PAS, Opinion and Order, at 29 (D.R.I. Sept. 4, 2014) ("slip op.") (describing trend towards non-cash forms of settlement). In many cases, brand-name companies have offered their generic rivals lucrative "side deals," such as the co-promotion and back-up manufacturing arrangements presented in *Actavis*. *See* 133 S. Ct. at 2229. In an increasingly common mechanism, the brand-name enters into a "No-AG commitment" — an agreement not to introduce an AG in competition with the generic manufacturer — in exchange for the generic's agreement to forestall its own entry.[7]

As noted, brand-name companies

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, 41-48. 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.* at iii; *see also id.* at 33.[8]

Accordingly, a No-AG commitment is highly lucrative to a first-filer generic company. 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 have made had it faced AG competition. *Id.* at vi; *see also infra* at 27. As the FTC's study further observed, the industry understands that a No-AG commitment can be a win-win for both 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. The potential victims in such arrangements are consumers, who end up paying far more than they would in a competitive market.

[8] 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.

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

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, through various side deals, to pay two generic companies in exchange for their agreements to stay off the market for nine 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 [illegible]

sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 2234. The payment "simply keeps prices at patentee-

"vexing" (*id.* at 26, 28). The court recognized that its holding would give drug companies "the obvious cue to structure their settlements in ways that avoid cash payments" but achieve the same anticompetitive ends. *Id.* at 25, 28. "When a patent holder pays a would-be generic competitor to stay out of the market — regardless of the form of the payment — value is exchanged and the brand manufacturer is able to continue on with fewer competitors." Slip op. at 30.

The district court acknowledged that court opinions have "diverge[d]" on whether reverse payments are limited to cash. *Id.* at 31. In fact, nine courts have addressed the issue. Seven have ruled that a reverse payment need not necessarily be cash, while only one agreed with the district court here. *See In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516-SRU, Order on Motion to Dismiss (D. Conn. Mar. 23, 2015) (cash not required); *United Food and Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, No. 14-md-02521-WHO, Order on Motion to Dismiss (N.D. Cal. Nov. 17, 2014) (same); *In re Effexor EX Antitrust Litig.*, No. 3:11-cv-05479-PGS, Order on Motion to Dismiss (D.N.J. Oct. 6, 2014) (same); *Time Ins. Co. v. AstraZeneca*, No. 2:14-cv-04149-GAM, Order on Remand (E.D. Pa. Oct. 1, 2014) (same); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389-PGS, Order on Motion to Dismiss (D.N.J. Sept. 12, 2014) (same); *In re Nias-9(N)-4(ias)-8(-94(p)8(74*

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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.* at 2236. Nothing in the *Actavis* decision suggests that the law governing such arrangements depends on the precise form of the compensation paid to achieve that "anticompetitive consequence." To the contrary, the reasoning in *Actavis* cuts squarely against that conclusion.

Second, the district court's logic violates the basic precept that antitrust liability principles turn on economic substance, not form. In particular, the court elevated form over economic substance when it concluded that reverse payments can trigger antitrust scrutiny only when they are made in cash rather than in the form of some non-cash economic equivalent. Its rationale would perversely allow parties settling patent litigation to avoid antitrust liability simply by sharing their enhanced monopoly profits in some 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 economic impact is the same — the drug companies benefit but consumers are harmed.

Finally, a settlement with a No-AG commitment

mutual non-

manufacturer to constitute a reverse payment." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

More fundamentally, confining *Actavis* to cases involving cash transfers would contradict the Supreme Court's precedential rationale for its holding. The Court relied heavily on prior decisions in which it had found settlement agreements anticompetitive and unlawful even though they involved no cash payment to the allegedly infringing party. *Actavis*, 133 S. Ct. at 2232-33; *see, e.g.*, *United States v. New Wrinkle*, 342 U.S. 371, 377-78 (1952) (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 where the payment is in cash.

Moreover, the *Actavis* framework is well equipped to evaluate whether non-cash compensation amounts to an unlawful reverse payment. As describe in *Actavis*, the analysis of these kinds of litigation settlements "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."

"[S]ubstance, not form," governs the antitrust inquiry. *American Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 195 (2010).

The district court likewise violated a core holding of *Actavis* when it elevated the "public policy favor[ing] the settlement of patent litigation" over antitrust concerns in all cases involving non-cash reverse payments in order to "preserv[e] for litigants a viable path to resolve their disputes." Slip op. at 25-26. As the Supreme Court explained, however, litigants already have viable settlement paths that do *not* generally pose antitrust concerns, such as agreements that merely fix a date of generic entry. *See Actavis*, 133 S. Ct. at 2237; *see also* p. 11, *supra*. In contrast, when a settlement agreement *does* involve "large and unjustified" compensation by the brand to the generic, the Supreme Court held without qualification that the "risk of 0 Td [()9(of 0 Td [o (n)-3(t)-3( )]T<vsi[-)-6(S)-2(. C)-2(t)-6(. a

special rule that applies only after the plaintiff has made some kind of threshold showing. Rather, the inquiry into whether the payment is "large" and "unexplained" is part of the rule-of-reason analysis itself. *Actavis*, 133 S. Ct. at 2236, 2237.[11] *See also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 9545, at *50 (E.D. Pa. Jan. 28, 2015) (rejecting argument that *Actavis* imposes a "threshold burden" before rule-of-reason analysis applies and considering whether payment is large and unjustified under "standard rule of reason analysis"); *Nexium*, 968 F. Supp. 2d at 386-87, 392 (applying rule-of-reason to No-AG reverse payment settlement).

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

In rejecting antitrust scrutiny for non-cash reverse payments, the district court not only contradicted the reasoning of *Actavis*, but also adopted a distinction between cash and non-cash payments that makes no *economic* sense. As the Supreme Court has long emphasized, antitrust analysis turns on economic

[11] *See also id.* at 2238 ("[T]rial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrubvvo0.01iboSooitrs to aubb(r)4(e)1vi( )9(a)t(r)9(412(d

substance, not form.[12] Here, it is not the form of the reverse payment that triggers antitrust concern, but the impact of that payment on consumer welfare. The No-AG commitment that Warner Chilcott gave to Watson

alleged here satisfy both conditions.[14] The agreement in this case plainly gave Watson something it could not have won in the patent litigation: the ability to insulate its generic product from competition with the branded drug company's authorized generic. Moreover, as alleged, the agreement maintains supracompetitive prices in which Warner Chilcott and Watson both share.

Warner Chilcott paid for that agreement with an economically consequential No-AG commitment. Under the FDCA, a brand-name manufacturer may introduce an AG product at any time

profits by inducing its first-filing rival to keep all generics off the market for an incremental period.

As noted, such No-AG commitments are highly valuable to the generic company. Typically, eliminating an AG during the first 180 days increases a first filer's revenue (such as Watson's in this situation) by approximately 65 to 100 percent. *AG Report* at 59. On a brand-name drug with one billion dollars in annual sales, the first filer will earn a conservatively estimated $255 million during the first 180 days of generic sales, if the branded-drug company agrees not to compete with an AG, but only $154 million, if an AG enters the market, a difference of $101 million:

These added revenues are not distinguishable in any economically significant way from the reverse payment analyzed in *Actavis*. The fact that the generic company obtains these additional revenues by selling its product does not make them comparable to the revenues that company would earn in a presumptively legal settlement in which the parties merely compromise on an entry date and the branded drug company pays no compensation to the generic. By giving up its unqualified right to earn profits from marketing its own AG product, the branded-drug company enables the generic to earn added revenues, thus

enable the factfinder to estimate the value of a No-AG commitment or other non-cash form of consideration to permit the requisite rule-of-reason analsyis.[16]

Finally, characterizing a No-AG commitment as a form of "exclusive license," as the defendants here did below, does not change the analysis.[17] As the Court reiterated in *Actavis*, "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." 133 S. Ct. at 2231.[18] True, most

[16] Although the district court believed that *Actavis* requires a coupngTBB(t)]TJ (oupn)5(i2n)5(

exclusive licenses in other contexts raise no antitrust concerns because they promote rather than reduce competition, such as by combining complementary assets.[19] Here, however, any "exclusive license" would simply take the form of a No-AG commitment, which does *not* promote competition and instead merely enlarges the pool of shared supracompetitive profits to the detriment of consumers. -o6t04 7 0 T

Compl. ¶ 90 (Warner Chilcott agreed not to launch AG until July 2014). When, as alleged 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.

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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June 16, 2015

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Attorney for Federal Trade Commission

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