In The

United States Court of Appeals

for the

First Circuit

Case No. 14-2071

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated,

Plaintiffs-Appellants

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31,

(continuation of caption on next page)

On Appeal from the United States District Court for the District of Rhode Island

BRIEF *AMICI CURIAE* ON BEHALF OF 70 LAW, ECONOMICS, AND BUSINESS PROFESSORS AND THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF APPELLANTS

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Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; WARNER CHILCOTT COMPANY; ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.,

Defendants-Appellees

Case No. 15-1250

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; END PAYOR PLAINTIFFS; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated;

MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE

BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS' INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; A. F. OF L. BUILDING TRADES WELFARE PLAN; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated,

Plaintiffs-Appellants

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; ALBERTSON'S, LLC; HEB GROCERY COMPANY. L.P.,

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.,

Defendants-Appellees.

CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

Pursuant to Fed. R. App. P. 26.1, Amicus Curiae American Antitrust Institute makes the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

   Amicus is a non-profit corporation, with no other entity having any ownership interest in it.

2) For non-governmental corporate parties please list all publicly held companies that own 10% or more of the party's stock:

   None.

/s/Kenneth A. Wexler

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INTEREST OF AMICI CURIAE

The academic *amici* are professors of economics, business, innovation, antitrust law, and intellectual property law. (A list of signatories is attached as Addendum A.) Their sole interest in this case is to ensure that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

Amicus American Antitrust Institute (AAI) is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici offer this brief because exclusion-payment settlements, by which brands pay generics to delay entering the market, are one of the most harmful

[1] All parties have consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(c)(5), *amici* state that no counsel for a party has authored this brief in whole or in part; and no party, party's counsel, or any other person or entity—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief. AAI's Board of Directors has approved this filing for AAI. Individual views of members of the Board of Directors or Advisory Board may differ from AAI's positions. Certain members of the Advisory Board or their law firms represent plaintiffs in this matter, but they played no role in the Directors' deliberations or the drafting of this brief.

forms of anticompetitive business behavior in today's economy. These agreements cause enormous harm, requiring consumers to overpay by billions of dollars and to miss dosages by splitting pills in half or not taking needed medications.

Exclusion payments today take myriad forms, including above-market-value business deals like those at issue in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), and numerous other types of transfers of substantial economic value. The Court in *Actavis* found that a large transfer of consideration from a brand to a generic, in exchange for the latter's delayed entry, could have "significant anticompetitive effects" and violate the antitrust laws. *Id.* at 2237. But this watershed ruling would be reduced to a dead letter if courts were to allow brands and generics to achieve the same anticompetitive ends merely by changing the form of the payment.

In holding that only cash payments are subject to antitrust scrutiny under *Actavis*, the court below applied a formalistic, stilted analysis that created a loophole large enough to accommodate an entire industry's worth of supracompetitive profits and missed dosages. Just as problematic, as explained fully below, the court's analysis purported to apply *Actavis* but was closer to defying it, in (1) limiting "payment" to cash, (2) using considerations that *Actavis* employed to *scrutinize* exclusion-payment agreements instead to *justify* them, (3) imposing astronomically high standards that plaintiffs will not be able to satisfy, and (4) ignoring essential *Actavis* holdings.

ARGUMENT

I. "PAYMENT" UNDER *ACTAVIS* IS NOT LIMITED TO CASH

In the landmark *Actavis* case, the Supreme Court for the first time considered the antitrust legality of agreements by which brands pay generics to delay entering the market. The Court forcefully held that such agreements could be "unjustified," 133 S. Ct. at 2235-36; have the potential for "significant adverse effects on competition," *id.* at 2234; and "violate the antitrust laws," *id.* at 2227.

Flying in the face of this ruling, the court below asserted that *Actavis* "fixates on the one form of consideration that was at issue in that case: cash." *In re Loestrin 24 FE Antitrust Litig*., No. 1:13-md-2472-S-PAS (D.R.I. Sept. 4, 2014), JA 001004. Moreover, "this fixation is apparent from the first paragraph of Justice Breyer's majority opinion" and is "just the tip of the iceberg." JA 001004-05. Although the court thought it would be "rash" to conclude, based on this language, that *Actavis* applied only to cash payments, it found that "more than merely the choice of words describing the consideration . . . suggests that the majority in *Actavis* intended for it to apply only to cash settlements." JA 001006. The court claimed that each of the factors in its antitrust analysis could only be applied to cash payments. JA 001006. And it asserted that its conclusion was "dictated by the language and meaning of *Actavis* and considerations of public policy." JA 001013.

The court below was wrong.[2] For starters, the *Actavis* case *itself* did not involve the payment of straight cash. The Federal Trade Commission ("FTC") in that case had alleged not that the brand made a naked cash payment to the generics for delayed entry, but that the brand had overpaid the generics for services not worth the amount paid. *Actavis*, 133 S. Ct. at 2229.

In addition, the *Actavis* majority opinion never used the word "cash." The majority twice used the phrase "millions of dollars"—once in describing a hypothetical example of a payment from "A" to "B," *id*. at 2227; and once in describing the overpayment from the brand in that case to the generics, *id*. at 2229. But the Court also twice used that same phrase in referring to the value to the generic manufacturer of not facing other generic competition during the 180-day period: "[T]his 180–day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id*. at 2229 (citation omitted). And again: "[T]he special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product . . . can be worth several hundred million dollars." *Id*. at 2235 (citation omitted). Indeed, emphasizing that substance, not form, matters, the Court noted that in challenging the above-market-value business deal, the FTC "alleges

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[2] *See generally* Michael A. Carrier, *How Not To Apply Actavis*, 109 NORTHWESTERN UNIVERSITY LAW REVIEW ONLINE 113 (2014) and Michael A. Carrier, *U.S. Court Issues Concerning Ruling on Drug Patent Settlements (Loestrin)*, E-COMPETITIONS BULLETIN, No. 69705 (Oct. 2014).

that, *in substance*, the plaintiff agreed to pay the defendants many millions of dollars . . . ." *Id*. at 2231 (emphasis added).

Can it possibly make economic sense to apply *Actavis* to preclude antitrust scrutiny where, instead of overpaying for services, the brand pays the generic with gold bullion or real estate? Or gives the generic a lucrative business deal for free? Or agrees not to compete with the generic in some other market? Or agrees not to launch its own generic, thereby handing the first filer "several hundred million dollars"? Certainly not. Indeed, the district court recognized the illogic of applying scrutiny only to cash payments, a conclusion it reached with "significant reservations" and which it called "vexing." JA 001013.

What matters for antitrust analysis is not a transaction's form, but its economic substance. The Supreme Court has consistently required that antitrust analysis "be based upon demonstrable economic effect rather than . . . upon formalistic line drawing." *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992) ("formalistic distinctions" are "generally disfavored in antitrust law"). For that reason, the only appellate court[3] and 8 of 9 district courts

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[3] *See In re Cipro Cases I & II*, 2015 WL 2125291 (Cal. May 7, 2015).

(not including the court below) that have considered the issue have found that "payment" is not limited to cash.[4]

Actavis made clear that lower courts have an important role to play in "structuring" the antitrust litigation. *Actavis*, 133 S. Ct. at 2238. This case calls upon this Court to continue the structuring recently begun by the *Cipro*, *Aggrenox*, *Lidoderm*, *Effexor*, *Time*, *Lipitor*, *Niaspan*, *Wellbutrin XL*, and *Nexium* courts by making clear that whether a payment invokes antitrust scrutiny under *Actavis* depends not on its form, but on its economic substance. And there can be no doubt that here, as in *Actavis*, the plaintiffs have alleged that "in substance, the [brand] agreed to pay the [generic] many millions of dollars." *Id.* at 2231.

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[4] *See In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516-SRU, 2015 WL 1311352, at *12 (D. Conn. Mar. 23, 2015); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (Lidoderm)*, No. 14-md-02521-WHO, 2014 WL 6465235, at *11 (N.D. Cal. Nov. 17, 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-05479-PGS, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca*, No. 14-cv-04149, 2014 WL 4933025, at *3 (E.D. Pa. Oct. 1, 2014); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 542 (D.N.J. 2014); *In re Niaspan Antitrust Litig.*, No. 13-md-02460, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014); *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-02431, slip op. at 4 (E.D. Pa. Jan. 17, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) (all interpreting payment to include non-cash compensation); *but see In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995-WHW, 2014 WL 282755, at *7 (D.N.J. Jan. 24, 2014), appeal docketed, No. 14-1243 (3d Cir. Jan. 30, 2014) (limiting payment to cash).

II. THE COURT BELOW APPLIED AN INAPPROPRIATE ANTITRUST FRAMEWORK

In considering the antitrust issues presented by exclusion-payment settlements, the court below applied an improper framework and made multiple errors within that framework.

The court below stated that "[o]stensibly to assist the lower courts, *Actavis* set forth five 'considerations' to guide the inquiry as to whether a settlement payment satisfies the rule of reason." JA 001006. It then discussed the five considerations, which centered on exclusion payments' (1) anticompetitive effects, (2) lack of justification, and (3) market power, along with (4) the feasibility of judicial analysis and (5) parties' ability to settle without payment. JA 001006-07.

Actavis did not, however, introduce these five considerations as the foundation of a new and unique rule-of-reason analysis. The Court's intended analysis followed the familiar antitrust framework that "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations." *Actavis*, 133 S. Ct. at 2231. Instead, the Court employed the five for a very different reason: as explanations showing why the "general legal policy favoring the settlement of disputes" did not displace ordinary antitrust analysis. *Id.* at 2234.

This was important. For the decade before the *Actavis* decision, most appellate courts that had considered exclusion-payment agreements had

immunized them largely based on the policy in favor of settlements, which conserve resources and provide certainty. To pick just two examples, the Eleventh Circuit in *Schering-Plough Corp. v. FTC* found that "[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits," 402 F.3d 1056, 1072 (11th Cir. 2005), and the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* highlighted the "long-standing policy in the law in favor of settlements, [which] extends to patent infringement litigation." 544 F.3d 1323, 1333 (Fed. Cir. 2008).

The influence of the pro-settlement policy explains why the Supreme Court tackled this argument head-on. To support its conclusion that the policy did not immunize exclusion-payment settlements, the Court employed five wide-ranging arguments. In case there were any doubt as to the Court's use of these explanations, it made clear that "these [five] considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements." *Actavis*, 133 S. Ct. at 2237. Applied to the case, the Court explained that "the FTC should have been given the opportunity to prove its antitrust claim." *Id.* at 2234.

In contrast to the Supreme Court's unmistakable use of the considerations to open a courthouse door that had been slammed shut by excessive deference to the policy supporting settlements, the court below used the arguments to conclude that

the plaintiffs should *not* be given an opportunity to prove their antitrust claim. In addition to using the five explanations for very different reasons than in *Actavis*, the court imposed astronomically high standards that future plaintiffs will almost never be able to satisfy. These problems become painfully apparent through analysis of each of the considerations.

First Consideration. The court below stated that, under *Actavis*, courts must compare "the anticipated supracompetitive profits associated with continued monopoly sale of the product and the sum paid to the generic competitor." JA 001006. The *Loestrin* court even claimed that it "would be all but impossible to assess the 'potential for genuine adverse effects on competition'" without making such a comparison. JA 001008.

The court erred by imposing hurdles never envisioned by *Actavis*. The Supreme Court never required a comparison of the brand's monopoly profits and the payment to the generic.[5] Instead, the Court highlighted the harms from payment and confirmed that the presence of multiple generics would not prevent brands from entering into settlements. It explained that a brand's payment is essentially "a purchase . . . of the exclusive right to sell its product" (which it would lose if it lost

[5] *See also* Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 RUTGERS UNIV. L. REV. (forthcoming 2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2560107 (draft at 12) ("*Actavis* never states that the value of the payment must be ascertained, but only that it must be shown to be above reasonably anticipated litigation costs.").

the patent litigation) and that "payment in return for staying out of the market [] simply keeps prices at patentee-set levels." *Actavis*, 133 S. Ct. at 2234.

To support its requirement for comparing monopoly profits and payment size, the *Loestrin* court quoted a passage from *Actavis* that a payment may "'provide strong evidence that the patentee seeks to induce the generic . . . to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.'" JA 001006 (citing *Actavis*, 133 S. Ct. at 2235). But this passage only references a brand's ability to use its monopoly profits to induce a generic to drop its claim. It does not even hint at precise calculations of monopoly profits and generic payment, let alone a comparison between the two.

Second Consideration. In analyzing the factor of unjustified anticompetitive effects, the court asserted that "without knowing the monetary value of the settlement payment, a plaintiff would be unable to demonstrate that the payment was 'unjustified' in light of 'traditional settlement considerations.'" JA 001008. But requiring *plaintiffs* to prove that the defendants' business deal exceeded "fair value" contravenes *Actavis*'s holding that *defendants* have the burden of proof on this procompetitive justification. *Actavis*, 133 S. Ct. at 2236-37 (placing burden on the "antitrust defendant [to] show in the antitrust proceeding that legitimate justifications are present" and noting that in some cases the defendant might be "unable to explain and to justify [its payment]"). And requiring

plaintiffs to negate this justification *in their complaint*, when defendants possess the evidence relating to the justifications for and valuations of the payment, does not make sense.

Third Consideration. The court limited the means by which plaintiffs could show that the patentee had market power. JA 001007. It stated that courts "must consider whether the size of the reverse payment indicates that the patentee held sufficient market power to 'work unjustified anticompetitive harm.'" JA 001007. And it asserted that not being able to show a precise value of the payment would prevent the payment's size from "be[ing] used as a proxy to measure the patentee's market power." JA 001008.

In *Actavis*, however, the Court used the third "factor" to show that the pro-settlement policy did not immunize settlements because plaintiffs could rely on payments themselves to show market power. The *Loestrin* court nonetheless worked backwards from its false premise that plaintiffs must demonstrate a payment of a certain size to show market power to the conclusion that *only* cash payments are subject to antitrust scrutiny because it is too difficult for courts to calculate the value of non-cash payments.

The Supreme Court, however, never stated or implied that the only way for a plaintiff to plead or prove market power was through the size of the payment. In fact, in addition to the payment, the *Loestrin* plaintiffs pled that "[a]t all relevant

times, [the brand's] price for Loestrin 24 has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs," and that the brand "has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives)." Consolidated Class Action Complaint ¶ 144, *In re Loestrin 24 FE Antitrust Litig*., MDL No. 13-2472-S-PAS (D.R.I. Sept. 4, 2014), JA 000165-66.

Fourth Consideration. The court imposed on plaintiffs the burden of demonstrating a precise value of the payment before they could use the payment as a "surrogate" for the patent's weakness. JA 001008. But such precision was nowhere required in *Actavis*, which supported the feasibility of antitrust actions on the grounds that "it is normally not necessary to litigate patent validity to answer the antitrust question" and that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Actavis*, 133 S. Ct. at 2236. In its quest for precision, the court below forgot that a large non-cash payment could provide evidence of a patent's weakness, even if that payment could not be converted with 100 percent certainty to the nearest dollar amount.

Fifth Consideration. The court below asserted that it needed to "assess the payment in light of the reasons given for its having been made." JA 001007. The

court claimed that "without a firm grasp of the monetary value of the settlement vis-à-vis the expected monopoly profits," it "would be difficult to discern whether the 'basic reason' for the settlement was a desire to maintain and share patent-generated monopoly profits." JA 001008.

Yet again, the court below misconstrued a consideration from *Actavis*. The Court in *Actavis* did not expect plaintiffs to demonstrate a precise settlement value and compare it to monopoly profits to discern the "basic reason" for the settlement. Nor did it anticipate an open-ended assessment of the reasons for the payment. Instead, the Court simply highlighted the need for antitrust liability when the settling parties seek to maintain and share patent-generated monopoly profits.

In short, the court below applied an antitrust analysis that used five "factors" in a manner directly contrary to the Supreme Court's opinion in *Actavis*. The Court applied these considerations to show that the policy in favor of settlement should not immunize exclusion-payment agreements and to allow the FTC to prove its case. In contrast, the court below used the "factors" to block plaintiffs from proving their cases, imposing the hurdle of calculating a "true value," and finding that in the absence of such proof, plaintiffs would not be able to show anticompetitive effects, unjustified payments, market power, patent weakness, or the "basic reason" for settlement.

III. THE COURT BELOW IGNORED CRUCIAL *ACTAVIS* HOLDINGS

The court below also erred in disregarding three essential holdings from *Actavis*, which addressed (1) the public policy in favor of settlement, (2) parties' inability to settle cases without exclusion payments, and (3) the burdens imposed on plaintiffs.

The first unheeded holding involved the Court's criticism of an excessive deference to the public policy reasons in support of settlement. As discussed above, this policy played a role in appellate courts' insufficient scrutiny of settlements in the decade before *Actavis*. The court below asserted that "the fact that the majority and the dissent recognize and promote the public policy value of patent settlements suggests that *Actavis* should be read to apply solely to the cash settlements that it describes, and to exclude non-cash settlements." JA 001012.

In fact, however, the *Actavis* Court exhaustively detailed why the policy in favor of settlement was not commanding enough to outweigh all the other policy considerations favoring antitrust scrutiny of exclusion-payment settlements. The *Loestrin* court's disregard of this holding was particularly ironic given *Actavis*'s invocation of five considerations to rebut the policy and the *Loestrin* court's own application of these "factors" (albeit for a contrary objective).

Second, the court below avowed that "there can be no dispute that the holding in *Actavis* and the abandonment of the scope-of-the-patent test will make it

more difficult for patent litigants to settle." JA 001012. In reaching this conclusion, the court oddly relied on an article written by a lawyer who has represented defendants in exclusion-payment settlement cases rather than the Supreme Court, which directly addressed the issue.[6]

Indeed, contrary to the district court's suggestion that the Supreme Court rendered non-cash settlements immune from antitrust scrutiny to "preserv[e] for litigants a viable path to resolve their disputes," JA 001012-13, *Actavis* made clear that the risk of antitrust liability from payment "does not prevent litigating parties from settling their lawsuit." *Actavis*, 133 S. Ct. at 2237. The Court pointed out that parties could pursue alternative forms of settlement, such as "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." *Id.* These agreements, by which brands and generics divide the patent term by selecting a time for generic entry, tend to reflect the odds of success in patent litigation (and thus do not present similar antitrust concern).[7] And the settlements are more than

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[6] *See* JA 001012 (citing Kevin D. McDonald, *Because I Said So: On the Competitive Rationale of* FTC v. Actavis, ANTITRUST, Fall 2013, at 36, 42 (noting representation of "defendants in all of the *Ciprofloxacin* cases" and in the *Nexium* case)).

[7] HERBERT HOVENKAMP ET AL., 1 IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3, at 15–45 (2d ed. Supp. 2012); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660 (2004).

possible—in fact, they are typical, as shown by a recent FTC report that more than 70% of settlements do not involve payment or delayed generic entry.[8]

Third, the court imposed inappropriate burdens on plaintiffs. It asserted that "each of the[] five factors requires, on the part of the plaintiff . . . an ability to assess or calculate the true value of the payment." JA 001008. The *Actavis* Court, however, never envisioned plaintiffs being charged with this task. Again, the Court offered five arguments to explain why the policy in favor of settlement did not immunize exclusion-payment agreements. And the Court placed the burden on the "antitrust *defendant* [to] show in the antitrust proceeding that legitimate justifications are present" and noted that in some cases the defendant might be "unable to explain and to justify [its payment]." *Actavis*, 133 S. Ct. at 2236-37 (emphasis added).

In addition to inappropriate burdens, the court below, as discussed above, raised the burdens to extremely high levels, requiring plaintiffs to show a payment's "true value" and asserting that the failure to make such a precise calculation would prevent them from showing each of the "factors" it expected plaintiffs to prove. JA 001008.

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[8] FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2013*, at 1-2 (2014).

The *Loestrin* court recognized that the excessive burdens it imposed on plaintiffs were not consistent with established pleading standards. In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court did not "impose a probability requirement," but required only "plausible grounds to infer an agreement" and "simply call[ed] for enough fact[s] to raise a reasonable expectation that discovery [would] reveal evidence of illegal agreement." JA 001014 (quoting *Twombly*, 550 U.S. at 556). In fact, the *Loestrin* court confessed that the plaintiffs had submitted "two robust complaints" containing "facts demonstrating illegal contracts or combinations in restraint of trade." JA 001014.

The court also conceded that the plaintiffs "(understandably) struggle[d] to affix a precise dollar value" to the brand's non-cash payment, and that "[t]his should come as no surprise because pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve." JA 001014.

Further arguing against itself, the court acknowledged that this was "particularly true" when a "settlement involves licenses and co-promotion arrangements for other drugs and a 'no authorized generic' agreement," as these arrangements make "even a ballpark estimate . . . difficult to conjure." JA 001014. In short, the *Loestrin* court recognized that plaintiffs would not be able to demonstrate a precise value for payment and that its ruling was not consistent with

the Supreme Court's opinion in *Twombly*. Despite acknowledging these legitimate concerns, the court nonetheless forged ahead by manufacturing out of whole cloth requirements of undue precision from *Actavis*. And it applied these creations to dismiss plaintiffs' claims even though it conceded that "the [p]laintiffs have adequately pled the existence of a Sherman Act § 1 violation." JA 001015.

* * *

In short, the district court's antitrust analysis is seriously flawed. The court (1) ignores economics, *Actavis*, and common sense in limiting "payment" to cash; (2) uses the five *Actavis* "factors" not to scrutinize exclusion-payment agreements but to justify them; (3) imposes unduly high standards that plaintiffs will be hard-pressed to satisfy, especially at the pleading stage; and (4) ignores essential *Actavis* holdings relating to settlement, the need for payment, and the parties' burdens.

When antitrust scrutiny of exclusion-payment agreements burst onto the scene 15 years ago, brands were paying cash to generics to delay entering the market. Times have changed. Settling parties are now stashing the payments in darker corners such as the above-market-value business deals in *Actavis*. None of this should dissuade courts from calling a payment what it is.

The court below conceded that it "is of relatively little import whether a payment for delay is made in the form of cash or some other form of consideration" since either scenario would allow a brand firm to "pay[] a would-be

generic competitor to stay out of the market" and threaten "significant adverse effects on competition." JA 001017. The court also lamented that its ruling would allow the settling parties to "evade Sherman Act scrutiny" as long as they "take the obvious cue to structure their settlements in ways that avoid cash payments." JA 001015.

The court was correct that exclusion-payment settlements have significant anticompetitive effects and that its formalistic ruling would lead to evasion. But it failed to realize that such an unfortunate outcome was the result of its own creation, in contradiction of *Actavis* and ordinary pleading rules. Affirmance of this ruling would render the landmark *Actavis* decision a dead letter. This Court should not follow such an ill-advised path.

CONCLUSION

For the reasons above, this Court should reverse the decision of the district court granting defendants' motion to dismiss.

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Respectfully submitted,

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