No. 23-410-cv(L)

23-418 (CON), 23-420 (CON), 23-423 (CON)

In the United States Court of Appeals for the Second Circuit

IN RE BYSTOLIC ANTITRUST LITIGATION

(Caption continued on inside cover)

On Appeal from the United States District Court
for the Southern District of New York
No. 1:20-cv-05735-LJL (Hon. Lewis Liman)

BRIEF *AMICUS CURIAE* OF THE NEW CIVIL LIBERTIES ALLIANCE AND THE INTERNATIONAL CENTER FOR LAW & ECONOMICS IN SUPPORT OF APPELLEES, URGING AFFIRMANCE

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CVS PHARMACY, INC., RITE AID CORPORATION, RITE AID HDQTRS. CORP., J M SMITH CORPORATION, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED, D/B/A SMITH DRUG COMPANY, KPH HEALTHCARE SERVICES, INC., INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, A/K/A KINNEY DRUGS, MAYOR AND CITY COUNCIL OF BALTIMORE, UFCW LOCAL 1500 WELFARE FUND, TEAMSTERS WESTERN REGION & LOCAL 177 HEALTH CARE PLAN, FRATERNAL ORDER OF POLICE, MIAMI LODGE 20, INSURANCE TRUST FUND, LAW ENFORCEMENT HEALTH BENEFITS, INC. TEAMSTERS LOCAL NO. 1150 PRESCRIPTION DRUG BENEFIT PLAN, TEAMSTERS LOCAL 237 WELFARE FUND AND TEAMSTERS LOCAL 237 RETIREES' BENEFIT FUND, ALBERTSONS COMPANIES, INC., H-E-B L.P., THE KROGER CO., AND WALGREEN CO., INC.,

Plaintiffs-Appellants,

v.

FOREST LABORATORIES, INC., FOREST LABORATORIES IRELAND, LTD, FOREST LABORATORIES HOLDINGS LTD., FOREST LABORATORIES, LLC, ALLERGAN SALES, LLC, ALLERGAN, INC., ALLERGAN USA, INC., ABBVIE, INC., WATSON PHARMA, INC., WATSON LABORATORIES, INC. (NY), WATSON LABORATORIES, INC. (CT), WATSON PHARMACEUTICALS INC., ACTAVIS, INC., TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMACEUTICALS LTD., TORRENT PHARMA, INC., AMERIGEN PHARMACEUTICALS LTD., AMERIGEN PHARMACEUTICALS INC., GLENMARK GENERICS, INC., USA, GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS S.A., HETERO LABS LTD., HETERO DRUGS LTD., HETERO USA INC., INDCHEMIE HEALTH SPECIALTIES PRIVATE LTD., ALKEM LABORATORIES LTD., ASCEND LABORATORIES, LLC, ANI PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (DE), TEVA PHARMACEUTICAL INDUSTRIES LTD., AND GLENMARK PHARMACEUTICALS LTD.,

Defendants-Appellees.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the New Civil Liberties Alliance (NCLA) and the International Center for Law & Economics (ICLE) state that they are nonprofit corporations organized under § 501(c)(3) of the Internal Revenue Code. Neither NCLA nor ICLE has a parent corporation, and neither has issued any stock owned by a publicly held company.

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INTERESTS OF *AMICI CURIAE* AND INTRODUCTION

The New Civil Liberties Alliance (NCLA) is a nonpartisan, nonprofit civil-rights organization devoted to defending constitutional freedoms from violations by the administrative state.[1] The "civil liberties" of the organization's name include rights at least as old as the U.S. Constitution itself, such as jury trial, due process of law, the right to be tried in front of an impartial and independent judge, and protection against government taking of private property without just compensation. Yet these self-same rights are also very contemporary—and in dire need of renewed vindication—precisely because Congress, administrative agencies, and even sometimes the courts have neglected them for so long. NCLA aims to defend civil liberties—primarily by asserting constitutional constraints on the administrative state.

The International Center for Law & Economics ("ICLE") is a nonprofit, non-partisan global research and policy center aimed at building the intellectual foundations for sensible, economically grounded policy. ICLE promotes the use of law & economics methodologies to inform public policy debates and has longstanding expertise in the evaluation of antitrust law and policy. ICLE has an interest in ensuring that antitrust promotes the public interest by remaining grounded in sensible legal rules informed by sound economic analysis.

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[1] No counsel for a party authored this brief in whole or in part, nor has any person or entity, other than *amici curiae* and their counsel, made a monetary contribution intended to fund the preparation and submission of the brief. All parties consented to the filing of the brief.

In establishing a patent system, Congress sought to spur invention of new and useful products by conferring property rights on those who, through investment of substantial time and resources, successfully develop such products. As evidenced by its *amicus curiae* filing in this case, the Federal Trade Commission has sought for decades to weaken the patent laws by invoking antitrust law to pare back the scope of the property rights conferred by Congress on pharmaceutical patent owners. The Supreme Court's decision in *FTC v. Actavis*, 570 U.S. 136 (2013), rebuffed those efforts to a significant degree. Appellants—the Direct-Purchaser Plaintiffs, the Retailer Plaintiffs, and the End-Payor Plaintiffs—largely parrot the FTC's misinterpretation of patent and antitrust law.

NCLA and ICLE have no connection, financial or otherwise, with any of the parties before the Court. They are filing this brief for the sole purpose of providing the Court with their economically informed assessment of relevant statutory principles. In particular, NCLA and ICLE agree with the district court's holding that, in determining whether a patentee's payment to an alleged infringer qualifies under the *Actavis* standard as "large," the proper focus is on the "net" payment to the alleged infringer (that is, the amount by which the payment exceeds the value of what the patentee receives in return), not the "gross" payment. *See* D. Ct. ECF 438 (Second Op.) at 15 n.9.

Based on NCLA's and ICLE's reading of the district court's opinions and the parties' briefs, *amici* agree with Appellees that the complaints fail to state claims upon which relief can be granted. However, because *amici* have not closely studied the patent-litigation settlement documents, they do not have a well-informed view on whether Appellants have met the antitrust pleadings standards established by *Bell Atlantic Corp. v. Twombly*, 530 U.S. 544, 556-59 (2007), and do not address that issue in this brief.

STATEMENT OF THE CASE

Bystolic is a prescription drug approved by the Food and Drug Administration for the treatment of high blood pressure. Forest[2] obtained two patents covering Bystolic: the "'040 Patent" (which issued in 2003 and expired in 2021) and the "'580 Patent" (which issued in 1998 and expired in 2015). In 2011, seven generic-drug manufacturers (the "Generic Manufacturers") filed Abbreviated New Drug Applications (ANDAs) with FDA, seeking authority to market generic forms of Bystolic. All seven ANDAs claimed that the '040 Patent and the '580 Patent were invalid and that their generic formulations would not infringe the patents. Those claims essentially forced Forest to file patent infringement suits against the seven

[2] The developers and marketers of Bystolic are collectively referred to herein as "Forest."

Generic Manufacturers (which it did in March 2012); otherwise, FDA could have immediately approved the ANDAs.

Over the course of the next 20 months, Forest entered into separate settlement agreements with each of the Generic Manufacturers. The litigation-settlement agreements were all lengthy and included a variety of side deals. Appellants allege that each included the following two terms: (1) Forest licensed each of the seven Generic Manufacturers to sell generic Bystolic beginning September 17, 2021 (three months earlier than sales would have begun had they awaited expiration of the '040 Patent); and (2) all seven agreed to drop their invalidity/noninfringement counter-claims and not to begin marketing until September 17, 2021—unless another one of the Generic Manufacturers entered the market earlier.

Appellants allege that Forest and the Generic Manufacturers violated federal and state antitrust laws by conspiring to restrain trade. They allege that the Generic Manufacturers agreed to delay their entry into the Bystolic market in return for large payments from Forest. In January 2022, the district court dismissed their complaints for failure to state a claim, with leave to file amended complaints. D. Ct. ECF 354 (First Op.).

Appellants filed amended complaints in February 2022, and Forest and the Generic Manufacturers again moved to dismiss the complaints. On February 21,

2023, the district court granted the motions and dismissed the complaints with prejudice. Second Op. at 3.

The court recognized that Forest, in connection with the patent-litigation settlements, entered into side deals that entailed payments to each of the Generic Manufacturers. It concluded, however, that Appellants' factual allegations failed to show that any of the side-deal payments were "large and unjustified," as those terms are defined in *Actavis*. *Id.* at 19. The Court explained that whether a payment is "large" within the meaning of *Actavis* should be determined based on the patentee's "net" payment (*i.e.*, the gross payment minus the value received in return). *Id.* at 15 n.9.[3] After carefully examining Appellants' factual allegations regarding the settlement agreements, the court concluded the allegations "d[id] not suffice to state a claim" because Appellants had "not asserted facts as to any of the factors that would suggest conduct inconsistent with a pro-competitive justification." *Id.* at 20.

SUMMARY OF ARGUMENT

Congress has long mandated that courts should strive to maintain a balance between the sometimes-competing claims of the patent law and antitrust law, and that antitrust law should not be used to shortchange the rights of patent holders. *Simpson*

[3] As the district court explained, "If the payment reflects fair value for goods or services, it would say nothing about the patentee's belief in the validity of the patent." *Ibid.*

v. Union Oil Co., 377 U.S. 13, 14 (1964). In its *Actavis* decision, the Supreme Court sought to maintain that balance in the context of drug-patent litigation settlements between brand-name and generic drug companies. It sought to steer a middle ground between the "presumption of unreasonable restraint" approach espoused by FTC and adopted by the Third Circuit,[4] and the "scope of the patent" test adopted by other federal appeals courts,[5] under which such "reverse payment" settlements were not subject to antitrust scrutiny so long as their anticompetitive effects did not extend beyond the exclusionary potential of the underlying patents. *Actavis*, 570 U.S. at 158-160.

The Court held that when a generic drug company agrees, in connection with a patent-litigation settlement, to drop its challenge to patent validity, the agreement is subject to antitrust scrutiny under a rule-of-reason analysis if, but only if, the settlement also includes an "unusual," "large," and "unjustified" "payment" from the brand-name drug company to the generic company. *Id.* at 147, 158. The Court explicitly rejected FTC's argument that "reverse payment settlement agreements are presumptively unlawful" and that such agreements should be examined under a "quick look" approach rather than applying "a rule of reason." *Id.* at 158-59.

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[4] *In re K-Dur Antitrust Litig.*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 570 U.S. 913 (2013).

[5] *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

Although the Court did not define with specificity when a settlement-agreement payment should be deemed "unusual," "large," and "unjustified" (and thus subject to antitrust scrutiny), it provided several guideposts to assist lower courts in making that determination. First, a payment is not "unjustified" if it consists of granting a license to market the patented product in advance of the patent expiration date. *Id.* at 158. Second, the Court held that a payment is not "large" (and thus not actionable under antitrust law) if it is less than the litigation expenses the brand-name company could be expected to incur if it did not settle. *Id.* at 159. Third, the magnitude of any payment from the brand-name company (whether provided in cash or in the form of a non-cash benefit) is to be measured by the "net" benefit (*i.e.*, the gross value of the benefit minus any goods or services the generic company is required to supply in return), not the gross value. *Id.* at 156. Determining whether a payment is "large" based solely on the amount of cash transferred to the generic company makes little sense, because that rule would not account for the many types of non-cash benefits that can flow between the parties. Fourth, a payment is not "unusual" or "unjustified" if it is one "supported by traditional settlement considerations." *Id.* at 154.

The guideposts cited above are highly relevant to the district court's decision that the complaints fail to state a cause of action. To survive the motion to dismiss, Appellants were required to allege facts sufficient to render plausible their claims that

the payments from Forest were "large"; and for purposes of determining whether a payment is "large," that figure is computed by subtracting, from the amount of cash paid by Forest, the value of goods and services Forest contracted to receive in return. Moreover, simply alleging facts showing that the cash paid exceeds the value of goods and services received in return does not suffice to demonstrate the requisite "large" payment; the payment is not "large" unless it exceeds the expected litigation costs saved by settling the lawsuit. Finally, entering into "side deals" in conjunction with a litigation settlement (deals that by definition entail benefits flowing from both settling parties) is a "traditional settlement consideration" and does not by itself provide cause to subject the settlement to antitrust scrutiny.

ARGUMENT

I. *ACTAVIS* REQUIRES COURTS REVIEWING PATENT-LITIGATION SETTLEMENTS TO BALANCE THE GOALS OF PATENT LAW AND ANTITRUST LAW

In *Actavis*, the Supreme Court addressed an FTC antitrust challenge to a patent-litigation settlement under which the patent holder, Solvay Pharmaceuticals, allegedly had agreed to make hundreds of millions of dollars in cash payments to several generic drug companies in return for those companies agreeing not to market generic versions of the patented drug for another nine years. The drug companies argued that the settlement should be immune from antitrust scrutiny because the settlement was within the scope of the patent; *i.e.*, the patent at issue was not scheduled to expire until

2021, while the agreement permitted the generic companies to begin marketing in August 2015—five-and-a-half years sooner. The Eleventh Circuit agreed with that position, concluding among other things that authorizing antitrust claims of that nature would not be worth the candle because of the expense and complexity of such litigation—it would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. *FTC v. Watson Pharmaceuticals*, 677 F.3d 1298, 1313-14 (11th Cir. 2012).

The FTC argued, on the other hand, that the "large and unjustified" cash payment from Solvay (that is, a payment not representing fair value for services rendered) indicated that Solvay was paying potential competitors not to enter the market. It argued, therefore, that the agreement should be *presumed* to constitute an illegal conspiracy in restraint of trade, subject to the defendants' right to attempt to demonstrate that the agreement actually promoted competition.

The Supreme Court rejected both arguments and instead adopted a compromise position that attempted to balance the competing demands of antitrust law and patent law. It concluded that litigation settlements in which the brand-name company transfers something of value to the generic company can "sometimes" be subject to antitrust scrutiny and can "sometimes" violate the antitrust laws. *Actavis*, 570 U.S.

at 141. The Court repeatedly stated that courts hearing antitrust challenges to patent-litigation settlement agreements must seek to "balance" the often-conflicting principles of antitrust and patent law. *See, e.g., id.* at 148 (describing decision in *United States v. Line Material Co.*, 333 U.S. 287 (1948), as an effort to "strike [a] balance" between "the lawful restraint of trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."); *ibid.* (stating that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent."). The Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" and thus subject a patent settlement to antitrust scrutiny—particularly when "parties may well find ways to settle patent disputes without use of reverse payments." *Id*. at 158.

The Court rejected the FTC's assertion that reverse-payment settlements are "presumptively unlawful" and that "courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Id*. at 158-59. The Court explained that "abandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick look' approach) is appropriate only where an observer with even a rudimentary understanding of economics would conclude that the arrangements in

question would have an anticompetitive effect on customers and markets." *Id*. at 159 (citation omitted).

The Court acknowledged the not-worth-the-litigation-candle dilemma highlighted by the Eleventh Circuit. *Id.* at 153. The settling parties have a complete defense to the antitrust claim if it is established that the patent at issue is both valid and infringed by the generic company's product. Under those circumstances, there can be no restraint of trade because, even in the absence of a settlement agreement, the generic product would never have been marketed before the patent expired. Yet the antitrust proceedings would become impossibly complex if patent validity had to be litigated in order to resolve whether the settling parties suppressed competition. To resolve that dilemma, the court adopted a compromise solution that allows antitrust challenges to go forward against *some* litigation settlements (those involving a large and unjustified "reverse payment") without requiring the plaintiff to directly establish the patent's invalidity (or requiring the defendants to defend the patent's validity):

> [A]n antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. ... That is because it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham). ... An unexplained large reverse payment itself would normally suggest that the patentee has *serious doubts* about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market.

Id. at 157 (emphasis added). The Court explained, "In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158.

As a further aspect of its compromise solution, the Court entirely exempted from antitrust scrutiny one form of payment that brand-name companies commonly provide to generic companies in connection with patent-litigation settlement agreements: a license to market the patented product in advance of the patent expiration date. *Id.* at 158. It is well accepted that such licenses can be *extremely* valuable to a generic drug company, particularly if it is the *only* generic company holding such a license. *See, e.g., id.* at 141. These valuable licenses could arguably be viewed as having been granted to induce the generic company to withdraw its invalidity counterclaim and agree not to enter the market before its license kicks in. The Court nonetheless gave a pass to "reverse" payments of this sort, perhaps because, although large, they have a pro-competitive aspect—they allow a second seller to enter the market.

II. UNDER *ACTAVIS*, THE MAGNITUDE OF THE PAYMENT TO AN ALLEGED INFRINGER—WHETHER IT IS LARGE—IS MEASURED BY THE "NET" BENEFIT CONFERRED, AFTER DEDUCTING THE VALUE OF GOODS AND SERVICES IT IS REQUIRED TO PROVIDE IN RETURN

Appellants have consistently asserted that their complaints satisfy *Actavis*'s "large" payment requirement by including factual allegations that Forest, in connection with its settlement agreements, paid large sums to each of the generic drug companies to purchase a variety of goods and services. That assertion is inconsistent with the theory under which *Actavis* authorized reverse-payment antitrust claims.

As explained above, *Actavis* recognized the impracticality of permitting reverse-payment antitrust claims to proceed based on direct evidence that the challenged patent is invalid. The Court adopted its "large" and "unjustified" payment standard as a surrogate method for establishing patent invalidity—or at least for establishing a substantial risk that the patent would be held invalid if the matter went to trial. And why did the Court believe that such evidence is an adequate substitute for direct evidence of patent invalidity? The Court explained, "An unexplained large reverse payment itself would normally suggest that the patentee has *serious doubts* about the patent's survival" and thus is willing to pay large sums to induce others not to compete and to drop their patent challenges. 570 U.S. at 157 (emphasis added).

That explanation is inapplicable to side deals entered into by the patentee to obtain goods or services at fair market value. Such side deals do *not* suggest that the

patentee has "serious doubts" about his patent's survival and is paying the alleged infringer not to compete. That inference can properly be drawn *only* if the patentee's payment significantly exceeds the fair market value of the goods or services it is procuring. Accordingly, for purposes of a reverse-payment antitrust claim, the district court correctly held that the magnitude of any payments to the alleged infringer should be calculated based on the "net" benefit conferred; that is, the gross payment should be reduced by the value of the goods and services that patentee contracted to receive. If the patentee is receiving goods or services at fair market value, then (for purposes of *Actavis*) the net benefit is zero and, by definition, the patentee has not made a "large" payment to the generic drug company.

In any event, it makes little sense to focus the antitrust analysis on the gross amount of *cash* payments made by a brand-name company, because the benefits conferred on generic drug companies by brand-name drug companies often consist of non-cash benefits. For example, in *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017), Pfizer, Inc. was alleged to have induced a generic drug company not to compete by agreeing to accept a damages settlement from the generic company (in connection with an unrelated patent-infringement lawsuit) for an amount far less than the antitrust plaintiffs believed Pfizer could have recovered. In *Impax Laboratories, Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021), FTC accused Impax, a generic drug

manufacturer, of agreeing not to compete in return for a very large non-cash benefit from the brand-name manufacturer: a no-authorized-generic agreement.[6] If the magnitude of the payment from the brand-name company to the generic-drug company is measured by the gross amount of cash paid, non-cash benefits of the sort at issue in *In re Lipitor* and *Impax* would not be subject to antitrust scrutiny. Yet it is well accepted among courts and scholars that *Actavis*'s constraints fully apply to non-cash benefits. *See, e.g.,* FTC Commissioner Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After* Actavis*: Three Questions and Proposed Answers*, at 5, Remarks at Antitrust Master Course VII (Williamsburg, Virginia, October 10, 2014) ("the question is not even a close one: *Actavis* clearly applies to reverse payment settlements involving non-cash compensation.").

In sum, to survive the motion to dismiss, Appellants were required to allege facts sufficient to render plausible their claims that the payments from Forest were "large"; and that figure is computed by subtracting, from the amount of cash paid by Forest, the value of goods and services Forest contracted to receive in return.

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[6] As noted in *Actavis*, federal law grants the first generic drug company to file an ANDA challenging patent validity a 180-day exclusive marketing period once it receives FDA marketing approval, during which period other generic companies may not market their product. 570 U.S. at 143-44. However, the brand-name company is normally permitted to market its own generic version of the drug during that 180-day period. When a brand-name company signs a no-authorized-generic agreement, it agrees not to market a generic drug during the 180-day exclusivity period—rendering that period significantly more profitable for the generic company.

Neither Appellants nor the FTC *expressly* challenge the district court's holding that a patent-settlement agreement is not subject to antitrust scrutiny unless the patentee's *net* payment to an alleged infringer (*i.e.*, the gross payment less the value of any goods or services provided in return) is "large." But their arguments that the complaints have adequately stated a claim for relief are largely dependent on a contention that allegations of large gross payments in excess of saved litigation expenses suffice to state a claim—and that the burden then shifts to Forest and the Generic Manufacturers to demonstrate that the payments were justified. Thus, for example, in characterizing the Supreme Court's *Actavis* holding, Appellants assert that the Court "did not require detailed allegations about why the value of services did not justify the cash payments." Appellants Br. at 22. Rather, Appellants assert, the Court:

> recognized the FTC's contentions that the services had "little value" and that the "true point of the payments was to compensate the generics" to delay their launch. [*Actavis*, 570 U.S.] at 145. The Court specifically recognized that defendants would have the opportunity to show legitimate justifications, if any, in the antitrust proceedings. *Id.* at 156. ... [R]everse payments [are] adequately alleged where plaintiffs plead that the brand manufacturer paid a generic more than the brand's saved litigation expenses for a generic entry date.

Ibid. Appellants pleaded facts alleging that Forest's side deals committed it to paying $15,000,000 over the course of seven years, an amount well in excess of its saved

litigation costs; according to Appellants, they are "not required" to allege anything else in order to survive a motion to dismiss. *Id.* at 23.[7]

For the reasons stated above, Appellants' contention cannot be squared with either *Actavis*'s language or its rationale for authorizing antitrust scrutiny of some—but not all—payments by patentees to potential competitors. Contrary to Appellants' contention, *Actavis* did not hold that a plaintiff's "little value" allegation must be accepted as true at the pleadings stage. Rather, the case came to the Supreme Court from an appeals court ruling that the FTC could not state an antitrust claim even if it adequately alleged that the patentee received *nothing* of value in return for its $300 million payment. The Eleventh Circuit held that "a reverse payment settlement is *immune* from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Actavis*, 570 U.S. at 146 (quoting *Watson Pharmaceuticals*, 677 F.3d at 1312) (emphasis added). The Court reversed that holding and remanded the case to the Eleventh Circuit "for further proceedings consistent with this opinion." *Id.* at 159. The Court never suggested that an antitrust plaintiff can survive a Rule 12(b)(6) motion to dismiss without alleging facts

[7] Similar arguments implicitly rejecting the district court's net-payment holding are scattered throughout Appellants' brief (*e.g.*, Pages 26, 33, and 39) and the FTC's brief (*e.g.*, Pages 12 and 14).

demonstrating that a patentee's net payment (gross payment minus value received in return) is large.

Appellants repeatedly refer to Forest's side-deal payment as "large" and "a reverse payment," and assert that *Actavis* imposes on Forest and the Generic Manufacturers the burden of demonstrating that those payments are justified. *See, e.g.*, Appellants' Br. at 30 ("Far from forbidding courts from putting the burden on defendants to justify reverse payments, that is squarely where *Actavis* put the burden."). Wrong. An antitrust plaintiff always "bears the initial burden of showing that the challenged action has had an actual adverse affect on competition as a whole in the relevant market." *1-800 Contacts, Inc. v. FTC*, 1 F.4th 102, 114 (2d Cir. 2021). In the *Actavis* context, the plaintiff's burden entails alleging facts sufficient to demonstrate the existence of a large reverse payment. And, as the district court explained, the plaintiffs' burden to demonstrate that a payment is "large" entails alleging facts plausibly demonstrating a large "net" payment.

III. A NET PAYMENT IS NOT "LARGE," AND THUS NOT ACTIONABLE UNDER ANTITRUST LAW, IF IT IS LESS THAN THE LITIGATION EXPENSES THE BRAND-NAME COMPANY COULD BE EXPECTED TO INCUR IF IT DID NOT SETTLE

As noted above, a large payment from a patentee to a generic-drug manufacturer in connection with a patent-litigation settlement agreement raises antitrust concerns when the payment suggests that the patentee has "serious doubts"

about the patent and is making the payment to induce the generic company not to compete. *Actavis*, 570 U.S. at 157. When, on the other hand, the evidence suggests that the patentee's payment was motivated by a desire to settle the case so as to avoid litigation costs, the antitrust laws are not implicated.

Actavis recognized "the desirability of settlement" of litigation and viewed it as a "strong consideration" in favor of the Eleventh Circuit's provision of "near automatic antitrust immunity to reverse payment settlements." *Id.* at 158. Litigation settlement is pro-competitive and permits businesses to turn their attention and resources to more productive activities. Settlement also saves litigation costs; Appellants agree that litigation costs during the relevant time period averaged $5-$6 million for each party in major pharmaceutical-patent litigation. *See* First Op. at 12. In recognition of the desirability of settlement as a cost-saving measure, *Actavis* held that reverse payments up to the amount of expected future litigation costs are justified and will not be viewed as evidence of an intent to suppress competition. *Id.* at 159.

Appellants nonetheless contended during district court proceedings that small reverse payments (*i.e.*, a reverse payment less than expected future litigation costs) could be actionable if evidence were introduced demonstrating that the payments were made for the purpose of suppressing competition. Any such argument is unwarranted

and misconceives *Actavis*'s rationale for permitting antitrust suits to proceed at all.[8] *Actavis*'s large-and-unjustified-payments test does not focus on *direct* evidence of competition-suppressing intent or patent invalidity. Rather, in an effort to prevent antitrust litigation from becoming too unwieldy, *Actavis* requires a focus on the magnitude of and justification for payments as "a surrogate for a patent's weakness." *Id.* at 158. If a payment to a generic-drug company is not large (a term that describes any net payment that is smaller than the litigation costs saved due to the settlement), it is not actionable.

Thus, if Appellants allege facts suggesting that Forest paid more than fair market value for the goods and services it contracted to receive in a side deal with one of the Generic Manufacturers, those allegations standing alone would not suffice to survive a motion to dismiss. Because Forest is entitled to pay each generic drug company its saved litigation costs in order to induce settlement, Plaintiffs would also need to show that the "net" reverse payment was "large"—that is, in excess of Forest's saved litigation costs.[9]

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[8] In a similar vein, Appellants erroneously assert throughout their brief that the complaints' allegations that the '040 patent was invalid (and would not have been infringed by the Generic Manufacturers) provides additional support for their antitrust claims. *See, e.g.*, Appellants Br. at 23.

[9] Recent scholarship indicates that limiting net payments from the brand-name manufacturer to the generic company to an amount no greater than saved litigation costs precludes a significant number of patent-litigation settlements that would lead

IV. *ACTAVIS* DOES NOT CALL INTO QUESTION ENTERING INTO SIDE DEALS, WHICH IS A TRADITIONAL MEANS WHEREBY PARTIES BRIDGE SETTLEMENT GAPS

Actavis noted the "general legal policy favoring the settlement of disputes," and explicitly acknowledged "the value of settlements." 570 U.S. at 153. The Court disclaimed any intent to question settlements that adopt "commonplace forms" and "traditional settlement considerations." *Id.* at 152, 154. Forest and the Generic Manufacturers thus cannot be faulted for seeking to settle their patent dispute on terms acceptable to all parties—provided only that the settlements do not include "large" and "unjustified" payments from Forest to the Generic Manufacturers.

In particular, they cannot be faulted for entering into side deals in connection with the settlements, whereby Forest contracted to purchase a variety of goods and services from the Generic Manufacturers. Such side deals are a common feature of settlement negotiations. *See id.* at 156 (describing "fair value for services" as part of "traditional settlement considerations"). They provide the parties with more items over which to negotiate and thereby increase the opportunity for the parties to bridge the gap between their respective negotiating positions. *Actavis* was decided based on

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to price reductions and enhanced consumer welfare. *See, e.g.*, Barry C. Harris, Kevin M. Murphy, Robert D. Willig, and Matthew D. Wright, *Activating* Actavis*: A More Complete Story*, 28 ANTITRUST 83 (Spring 2014). In light of that scholarship, there can be no justification for *cutting back* on *Actavis*'s holding that net payments that do not exceed saved litigation costs are immune from antitrust challenge.

the assumption that it would still be possible for litigants to settle pharmaceutical patent-infringement litigation. Nor can patentees, whose patents are presumptively valid and who have a strong interest in defending their property rights, be faulted for doing whatever they can (within the bounds of *Actavis*) to seek to settle the litigation under terms that maintain the exclusive marketing rights granted to them by the government-issued patent. Appellants' efforts to create new obstacles to settlement by questioning the propriety of fair-market-value side deals find no support in *Actavis*, which explicitly cited side deals as an innocent explanation for payments from a brand-name company to a generic-drug company. *Id.* at 156 (stating that such payments "may reflect compensation for other services the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. ... Where a reverse payment reflects *traditional settlement considerations*, such as avoided litigation costs or *fair value for services*, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.") (emphasis added).

Parties to pharmaceutical patent litigation already face immense obstacles to reaching settlements that comply with current antitrust standards. Those obstacles are the result of unique litigation dynamics created by the Hatch-Waxman Act, Pub. L. No. 98-417 (1984). Unlike the defendants in patent-infringement litigation that arises

in other contexts, a generic-drug company that initiates infringement litigation (by filing a "Paragraph IV certification" with FDA and thereby essentially forcing a brand-name company to file an infringement lawsuit) cannot be held liable for damages because it has not yet marketed any infringing products.[10] Thus, generic-drug companies sued for patent infringement generally cannot be induced to settle by an offer to waive damage claims, yet *Actavis* and potential antitrust liability severely limit use of the other most obvious settlement inducement—offering cash payments.

Of course, no litigant will agree to a settlement unless he perceives that it is advantageous. If waiving damage claims and making cash payments are off the table, settling patent-infringement litigation becomes extremely difficult. Entering into mutually beneficial side deals is one of the few remaining settlement options.

Yet, if Appellants have their way, a patentee will be unable to offer anything of value to a generic-drug company (other than a marketing license) without facing antitrust scrutiny. *See* Appellees Br. 20; *see also* Second Op. at 15 n.9. And without the ability to offer anything of value, no matter how commonplace such offers may be among negotiators, there will be few of the settlements that *Actavis* sought to encourage.

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[10] In contrast, patent-infringement litigation arising in other contexts generally involves defendants who are alleged to be committing more concrete infringing acts. Such defendants face severe, potentially-bankrupting damages awards if the trial court sustains the infringement claims.

As Judge Posner has cogently observed:

> [A]ny settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill.2003).

CONCLUSION

NCLA and ICLE respectfully request that the judgment of the district court be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of July, 2023, I electronically filed the *amicus* brief of NCLA, *et al*., with the Clerk of the Court for the U.S. Court of Appeals for the Second Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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CERTIFICATE OF COMPLIANCE

I am an attorney for *amici curiae* New Civil Liberties Alliance and International Center for Law & Economics. Pursuant to Fed.R.App.P. 32(a)(7), I hereby certify that the foregoing brief of *amici curiae* is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect 2021), the word count of the brief is 5,562, not including the table of contents, table of authorities, certificate of service, and this certificate of compliance.

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