23-410 (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 continues on inside cover)

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

**BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION
IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL**

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(*Continued from front cover*)

Watson Laboratories, Inc.,

Debtor.

CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Hdqtrs. Corp., J M Smith Corporation, on behalf of itself and all others similarly situated, DBA Smith Drug Company, KPH Healthcare Services, Inc., individually and on behalf of all others similarly situated also known as Kinney Drugs, Inc, 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., Walgreen Co.,

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., AmerigenPharmaceuticals 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., Glenmark Pharmaceuticals Ltd.,

Defendants - Appellees.

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INTRODUCTION

Competition from generic drugs saves the U.S. health care system hundreds of billions of dollars annually.[1] To encourage competition, Congress established a mechanism that enables generic drug manufacturers to challenge patents associated with brand-name drugs. In some cases, parties have settled the resulting patent dispute with an agreement in which the brand-name drug manufacturer makes a "reverse payment," yielding a highly unusual arrangement in which "a party with no claim for damages"—the generic company being sued for patent infringement—"walks away with money simply so it will stay away from the patentee's market." *FTC v. Actavis, Inc.*, 570 U.S. 136, 152 (2013).

Reverse payments raise antitrust concerns because they can "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. Some reverse payments involve naked cash transfers, while others are clothed in pretextual side deals for goods or services. Both can harm competition.

In *Actavis*, the Supreme Court held that when the "basic reason" for a reverse payment is to "prevent the risk of competition," the payment is unlawful. *Id.* at 157-59. A "large" reverse payment that is "unjustified" by "traditional

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[1] *See* Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (Sept. 2022) ("Total generic and biosimilar savings in 2021: $373 billion.").

settlement considerations," such as saved litigation costs, is prima facie evidence of anticompetitive harm. *Id.* at 156-59.

Plaintiffs here allege that Forest, maker of the branded high blood pressure drug Bystolic, paid six would-be generic rivals to stop challenging Forest's patents and refrain from selling their products for at least eight years. Most of the payments took the form of contemporaneous side deals between Forest and the generic companies that were, according to plaintiffs, a disguise for Forest's inducements. Although the district court found that Forest had made "large" reverse payments in five of the six arrangements, it concluded that plaintiffs had failed to plausibly allege that those payments were unjustified. The court dismissed the complaints with prejudice.

The Federal Trade Commission has primary responsibility for federal antitrust enforcement in the pharmaceutical industry. We submit this amicus brief because we believe that the district court's ruling is inconsistent with *Actavis*, other antitrust precedent, and the law of pleading.

Under these authorities, plaintiffs can plead a side-deal reverse payment is "unjustified" when they allege peculiar circumstances supporting the inference that the goods or services at issue do not fully explain the payment. Here, plaintiffs met that burden by alleging, among other things, that Forest's many side deals were all (in the district court's words) "related to" the generic companies' commitments to

stay off the market and that each individual deal lacked key attributes of a freestanding business arrangement. Plaintiffs allege, for example, that Forest had no prior interest in the side deals, had no need for them, eschewed the typical formalities characteristic of such agreements, and failed to seek competing bids.

Those well-pleaded allegations sufficed to state a claim. But the district court rejected them by proffering its own procompetitive explanations for the side deals and finding that the complaints failed to refute those explanations. This approach contravened *Actavis*, which places the burden on *defendants* to "show … that legitimate justifications are present." 570 U.S. at 156. The court also failed to grant reasonable inferences in plaintiffs' favor and compartmentalized plaintiffs' allegations rather than assessing the complaints in full context.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC is an independent federal agency charged with promoting fair competition. As exemplified by its role as petitioner in *Actavis*, the Commission uses its law enforcement authority to challenge anticompetitive pharmaceutical patent settlements administratively and in federal district courts.[2] In addition, the

[2] *See, e.g.*, *Impax Labs., Inc. v. FTC*, 994 F.3d 484, 493 (5th Cir. 2021); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *In re AndroGel Antitrust Litig. (No. II)*, No. 1:09-cv-955-TWT, 2018 WL 2984873, at *1 (N.D. Ga. June 14, 2018).

Commission files *amicus curiae* briefs in pharmaceutical antitrust litigation[3] and has issued empirical studies addressing the competitive effects of generic substitution for brand-name drugs.[4] The Supreme Court and other federal courts have relied on those studies. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 n.21 (3d Cir. 2015). The FTC also reviews and publishes data regarding patent settlement agreements between drugmakers filed pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. *See* Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2461-64 (codified at 21 U.S.C. § 355 note).

Because the Commission has a strong interest in ensuring the proper application of the antitrust laws, and *Actavis* specifically, we respectfully submit this brief under Federal Rule of Appellate Procedure 29(a). The district court's

[3] *See, e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 59-60 (1st Cir. 2016).

[4] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

ruling, unless corrected, threatens to impair the effective enforcement of antitrust laws in the pharmaceutical industry. The court prematurely decided complex factual questions that require expert analysis and consideration of evidence solely in defendants' possession. The ruling could make it prohibitively difficult to plead an antitrust violation under *Actavis*, even when (as here) the alleged facts strongly suggest that the parties colluded to preserve a brand-name monopoly and split the profits.

BACKGROUND

A. Drug Makers Can Use Side Deals To Disguise Anticompetitive Reverse Payments

Brand-name drugs are often covered by patents, which "may or may not be valid, and may or may not be infringed." *Actavis*, 570 U.S. at 147. When a potential generic rival challenges those patents, the parties have an incentive to reach a settlement in which the brand manufacturer pays to keep the generic "out of the market." *Id.* at 154. The patentholder avoids a potentially devastating challenge to its patent-based monopoly profits, and the challenger may make more money by splitting the monopoly profits than it would by winning its patent challenge and selling generic drugs. *Id.* In the process, "[t]he patentee and the challenger gain; the consumer loses." *Id.*

The form of reverse-payment arrangements has evolved over time. The earliest involved the brand company compensating the generic company with cash.

After the FTC and private plaintiffs began challenging these agreements, brand and generic companies began to disguise the payments using side deals. These deals are typically negotiated and entered contemporaneously with a patent settlement and may involve the brand company ostensibly paying the generic for a product or service—for example, supplying raw materials, developing products, or selling intellectual property. *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009).

When a side deal involves a brand company making a payment that is disproportionate to the product or service it received, the "true point of the payment[]" may be "to compensate the generics for agreeing not to compete." *Actavis*, 570 U.S. at 145. *Actavis* itself involved side deals in which the brand paid the generic for services that allegedly had "little value." *Id.* As the Commission has explained, when a side deal has "peculiar circumstances"—such as an abbreviated timeline, lack of prior interest, or inconsistency with industry standards—this "suggest[s] that the agreement may have been a means of masking value transferred in exchange for eliminating the risk of competition." *In re Impax Labs., Inc.*, 2019 WL 1552939, at *21 (F.T.C. Mar. 28, 2019), *aff'd* 994 F.3d 484 (5th Cir. 2021).

Side deals are highly unusual. Outside the context of settling patent disputes, brand companies rarely seek the assistance of generic firms "with the activities that form the basis of side deals." Hemphill, 109 Colum. L. Rev. at 666. And even in the patent settlement context, side deals are very uncommon. In fiscal years 2016 and 2017 (the latest for which the FTC has published data), only two of 458 pharmaceutical patent settlements—less than 0.5%—included a side deal.[5]

B. Principles For Analyzing Reverse-Payment Settlements

Actavis held that reverse payments—whether involving naked cash or purported side deals—are subject to antitrust scrutiny because they have the "potential for genuine adverse effects on competition." 570 U.S. at 154 (quoting *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)), 158-60. Antitrust liability turns on the "basic reason" the parties agreed to a reverse payment. *Id.* at 158. If "the patentee seeks to induce the generic challenger to abandon its claims

[5] *See* Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition at 1-2 (two side deals), *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf; Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition at 1-2 (zero side deals), *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

with a share of its monopoly profits that would otherwise be lost in the competitive market," *id.* at 154, then "the antitrust laws are likely to forbid the arrangement," *id.* at 158. Conversely, where the payment to the generic reflects "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." *Id.* at 156. Courts faced with reverse-payment claims must therefore assess whether the payment is both "large" and "unjustified" by these other explanations. *Id.* at 157-58.

That analysis takes place as part of the antitrust rule of reason, which *Actavis* held applies to reverse-payment claims. *Id.* at 158-60. Under that framework, the plaintiff first must prove that a practice has an anticompetitive effect, either directly (*e.g.*, through increased prices) or indirectly through "proof of market power plus some evidence that the challenged restraint harms competition." *See Ohio v. American Express Co.*, 138 S. Ct. 2278, 2284 (2018). If the plaintiff does so, the burden shifts to the defendant to "show a procompetitive rationale." *Id.* If the defendant makes that showing, the burden shifts back to the plaintiff to show that the procompetitive benefits "could be reasonably achieved through less anticompetitive means." *Id.*

Actavis clarified that under the rule of reason, a plaintiff can show that a reverse-payment settlement is anticompetitive without "present[ing] every possible

supporting fact or refut[ing] every possible pro-defense theory." 570 U.S. at 159. Rather, "there is always something of a sliding scale in appraising reasonableness." *Id.* (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 780 (1999)).

C. Proceedings Below

Defendant Forest sells brand-name Bystolic, which treats high blood pressure. D. Ct. ECF 427 ("Compl.") ¶ 1. Plaintiffs allege an unlawful scheme in which Forest colluded with the six generic-company defendants—Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, and Watson—to delay competition for generic versions of Bystolic. *Id.* ¶ 3. The generic companies had challenged Forest's Bystolic patents, seeking to market their products before the patents expired. *Id.* ¶¶ 139-40. Between October 2012 and November 2013, all six generic companies agreed to abandon their patent challenges and defer entering the market for Bystolic until September 17, 2021. *Id.* ¶¶ 152, 163, 176, 181, 188, 195, 200.

At the time it entered these settlements, Forest paid the generic companies cash to cover litigation expenses and executed contemporaneous side deals under which it agreed to pay them millions of dollars more. Although the side deal payments were ostensibly for various goods or services,[6] plaintiffs allege that the

[6] Nominally, Forest paid Hetero to supply raw materials; Torrent to acquire patents; Alkem/Indchmie to supply other drugs; Glenmark for the right to jointly develop other products; Amerigen to invest in drug development efforts; and Watson as a loan in exchange for releases from pre-existing obligations.

circumstances of the deals—individually and collectively—demonstrate that none was a "*bona fide* business arrangement" and all were, instead, "pretextual" ways for Forest to mask reverse payments. *Id.* ¶¶ 154-59, 163-228. Plaintiffs allege that the arrangements violated the antitrust laws. *See, e.g.*, *id.* ¶¶ 256-61.[7]

The district court dismissed the complaints for failure to state a claim. The court did not take issue with plaintiffs' allegations that Forest enjoyed a monopoly in the relevant market. Compl. ¶¶ 238-53. The court purported to accept the truth of plaintiffs' allegations that Forest's settlements and side deals with each generic company were "related to one another" and that five of these six arrangements contained a "large reverse payment." D. Ct. ECF 354 ("First Op.") 33, 37, 44, 48, 50, 52. The court also appeared to credit plaintiffs' allegations that: (1) side deals are "common" ways to disguise reverse payments; (2) brand companies overpaying generic companies for the types of goods or services Forest purportedly purchased here are the "most common" type of pretextual side deal; and (3) brand and generic companies "seldom" enter into business arrangements of this sort when not settling patent litigation. D. Ct. ECF 438 ("Second Op.") 5.

The district court, however, concluded that plaintiffs had not plausibly alleged that any of the large reverse payments were unjustified. Purporting to apply

[7] Although plaintiffs allege that the Commission investigated the Bystolic side deals, Compl. ¶ 198, this should not be construed as a determination that violations did or did not occur.

Bell Atlantic Corp. v. Twombly, 550 U.S. 554 (2007), the court held that pleading an unjustified reverse payment under *Actavis* required plaintiffs to "show the absence of one or more factors that would be consistent with a pro-competitive justification" for the payments. Second Op. 17. The court went on to proffer its own procompetitive justifications for the side deals and find that the complaint allegations had failed to disprove them.

For example, the court found that Forest's purported joint development agreement with Glenmark "gave Forest a seat at the table and an opportunity to learn from and exploit Glenmark's expertise and know-how," *id.* at 40, refusing to credit plaintiffs' allegations that (1) Forest had shown no interest in this agreement before the patent settlement; (2) full payment was due even if the venture failed; and (3) the parties valued the relevant rights at $6 million when Forest paid $15 million. *Id.* at 38-43. Likewise, the court found that Forest's side deal to obtain ingredients from Hetero provided "obvious benefit[s]" to Forest, despite plaintiffs' allegations that Forest had no need for those materials, paid an excessive price, and never sought bids from other suppliers. *Id.* at 21-24.

The district court also found that some of plaintiffs' allegations of suspicious circumstances, like the fact that Forest and Amerigen did not finalize their side deal until after the FTC began investigating the arrangement, were "equally consistent" with an innocuous explanation. *Id.* at 47. And it rejected some

allegations, such as the fact that Forest had not previously expressed interest in drug supply from Alkem/Indchemie, as conclusory. *Id.* at 37.

This appeal followed.

SUMMARY OF ARGUMENT

1. Plaintiffs challenging a reverse payment need only plead market power and facts from which a court can infer that a large and unexplained reverse payment was tendered. *Actavis* placed the burden of establishing procompetitive justifications for a reverse payment principally on "[a]n antitrust defendant." 570 U.S. at 156. This rule makes sense because defendants often have exclusive possession of information regarding potential justifications. With respect to side deals specifically, courts agree that plaintiffs need only identify peculiar circumstances that support the inference that the goods or services at issue do not fully explain the payments.

Plaintiffs have met these standards. Plaintiffs allege that Forest, a monopolist drug patentholder, made large reverse payments to at least five separate generic companies as part of settlements keeping those companies from introducing rival products for at least eight years. Plaintiffs further allege that Forest made these payments via side deals that were unusual and lacked obvious procompetitive rationales. Taken together, those allegations create a plausible inference that Forest unlawfully paid the generics not to compete.

2. When the district court dismissed these allegations, it contravened *Actavis* and general rules of pleading. The court articulated its own procompetitive explanations for the side deals and faulted plaintiffs for not refuting them. But "*Actavis* does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256 (3d Cir. 2017).

In deeming the side deals procompetitive, the district court improperly found facts contrary to the complaint allegations and failed to draw all reasonable inferences in plaintiffs' favor, as the law requires. Instead, the court reasoned that plaintiffs' allegations could have also been "consistent" with innocuous behavior, *see, e.g.*, Second Op. 21, 26, 30, 47, and found that the "*more plausible* reading of the[] facts" supported defendants, *id.* at 32 (emphasis added). But a district court may not dismiss a complaint on such a basis; ascertaining which side's case is more plausible is the purpose of discovery, summary judgment, and trial. The court also unfairly faulted plaintiffs for not producing evidence at the pleading stage. And it failed to assess the allegations of the complaints as a whole, instead focusing on granular allegations about each side deal while overlooking the complaints' description of the suspicious context in which those deals were struck.

ARGUMENT

I. Plaintiffs Stated A Plausible Claim That Forest Paid The Generic Companies Not To Compete

Under *Actavis*, a plaintiff alleging that a side deal constitutes an unjustified reverse payment must allege facts that, taken together, support a reasonable inference that the side deal was not a freestanding business arrangement. Plaintiffs easily met that standard, and the district court erred by failing to recognize it.

A. Under *Actavis*, Plaintiffs Need Only Plead Market Power And Facts Allowing An Inference That A Large And Unjustified Reverse Payment Was Tendered

A complaint challenging a reverse payment states a claim if it alleges market power and "facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment." *FTC v. AbbVie Inc.*, 976 F.3d 327, 351 (3d Cir. 2020) (quoting *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 252 (3d Cir. 2017)). Courts have consistently recognized that the threshold for pleading that a payment is unjustified is a modest one, for three reasons.

First, *Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*." *Lipitor*, 868 F.3d at 256-57. *Actavis* explained that "[a]n antitrust defendant may show … that legitimate justifications are present, thereby explaining the presence of the challenged term and showing [its] lawfulness." 570 U.S. at 156. The Court added that "one who makes such a [reverse] payment may be unable to explain and to justify it." *Id.* at 158. This is

consistent with the rule-of-reason burden-shifting framework, under which procompetitive justifications are "question[s] of fact" that are only considered in response to a plaintiff's initial case and are "not cognizable in support of a motion to dismiss." *Covad Comms. Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005); *see In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 239 (S.D.N.Y. 2019) ("[A]ny procompetitive justification for such restrictions is not appropriately weighed on a motion to dismiss.").

Second, the information necessary to assess potential justifications for a side deal is normally "under the defendant's control" and unavailable to plaintiffs before discovery. *See Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 464 (7th Cir. 2020). The public will typically lack significant information about a brand's need (or lack thereof) for the services provided in a side deal, whether the negotiations were consistent with industry norms, and even the substance of the deal itself. It is not reasonable to expect plaintiffs to "pre-emptively refute evidence of value not in their possession or control." *In re Impax Labs., Inc.*, 2019 WL 1552939, at *19 (F.T.C. 2019), *aff'd* 994 F.3d 484 (5th Cir. 2021). Doing so would erect an insurmountable bar to meritorious antitrust cases, harming the public. Accordingly, the First Circuit declined to require "very precise and particularized estimates of fair value" at the pleading stage because those "may require evidence in the

exclusive possession of the defendants, as well as expert analysis." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016).

Third, the mere presence of a reverse payment is highly unusual. As *Actavis* observed, reverse-payment settlements are essentially unique to the pharmaceutical industry. 570 at 141, 147. Even there, reverse-payment settlements are rare. *See id.* They are also unnecessary for effective settlement. Extensive data confirms that "parties can—and do—settle without the brand company paying its potential generic competitor." Fed. Trade Comm'n, *Then, now, and down the road: Trends in pharmaceutical patent settlements after* FTC v. Actavis (May 28, 2019).[8]

For these reasons, courts have generally recognized that a plaintiff's initial burden to plead that a side-deal reverse payment is "unjustified" is a low threshold. In *Lipitor*, the Third Circuit revived allegations that a brand drug maker had paid a potential generic competitor by releasing a claim for damages it had against the generic in a different litigation. 868 F.3d at 253-54. The defendants argued that plaintiffs' complaint omitted important "context" that explained the payment. *Id.* at 256. But the court was unpersuaded, recognizing that "*Actavis* does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss." *Id.* Rather,

[8] *Available at* https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis.

"an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment," which the *Lipitor* plaintiffs had done. *Id.* at 256-58.

Subsequently, in *AbbVie*, the Third Circuit again reversed the dismissal of a reverse-payment claim—this time concerning a side deal in which the brand agreed to supply a different drug product to the generic at a favorable price. *See* 976 F.3d at 344-45. The court emphasized that a plaintiff need not "preempt every possible explanation" to plead a *prima facie* case under *Actavis*. *Id.* at 356 (cleaned up). And it rejected the lower court's reasoning that the side deal might be justified by the fact that the generic paid the brand for the drug supply, explaining that while "perhaps . . . a valid defense," that determination would require "factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage." *Id.* at 359 (quoting *Lipitor*, 868 F.3d at 261). To withstand dismissal, the FTC needed only to have alleged facts suggesting that the side deal was "unusual" and "c[ould] not be explained as an independent business deal." *Id.* at 357.

Most district courts have taken a similar approach. The court in *In re Niaspan Antitrust Litigation*, 42 F. Supp. 3d 735 (E.D. Pa. 2014), acknowledged that plaintiffs' allegations concerning a "spurious" side deal lacked "exquisite detail," and that defendants may ultimately be able to rebut them. *Id.* at 752-53. But the court nevertheless held that "*Twombly* does not require an antitrust plaintiff

to plead facts that, if true, definitively rule out all possible innocent explanations" for a reverse payment. *Id.* at 753. Likewise, in *In re Opana ER Antitrust Litigation*, 162 F. Supp. 3d 704 (N.D. Ill. 2016), the court declined to consider justifications at the pleading stage because "to establish conclusively that the payment . . . was made for procompetitive reasons, the Court would need to make inferences from the allegations in the complaints in [d]efendants' favor." *Id.* at 719. And in *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224 (D. Conn. 2015), the court denied a motion to dismiss because arguments about valuation of and justifications for the side deal were "sufficiently factual to require discovery." *Id.* at 244-45.

B. Plaintiffs Met Their Pleading Burden By Plausibly Alleging That Forest Made Large, Unusual Reverse Payments

The complaint allegations state a plausible *Actavis* claim. Forest allegedly was a monopolist in the relevant product market. *See* Compl. ¶¶ 238-53. The court found that plaintiffs had plausibly alleged that Forest entered a series of patent settlement agreements keeping six separate generic companies off the market for eight years; that each settlement included a "related" contemporaneous side deal; and that five of those arrangements included a "large reverse payment." First Op. 33, 37, 44, 48, 50, 52.[9] The court also appeared to credit plaintiffs' allegations that side deals "common[ly]" mask reverse payments, that side deals of the sort at issue

[9] The district court held that Forest's arrangement with Watson did not amount to a large reverse payment. Second Op. 47-51; Compl. ¶¶ 211-15.

here are the "most common" types for disguising reverse payments, and that such deals are "seldom" entered otherwise. Second Op. 5.

These allegations alone raise serious red flags. As plaintiffs explain, "[i]f Forest had been truly interested in entering into legitimate business partnerships with the Generic Defendants … common sense dictates that Forest would have done so prior to and separate from the settlement of the … Patent Litigation." Compl. ¶ 158. This claim would have force when describing a single side deal; here, Forest made at least *five* separate, lucrative arrangements with generic rivals—all "related to" (First Op. 33) those rivals' commitments not to compete until an identical date eight years later. The large number of side deals, all linked to eight years of deferred competition, makes it even more plausible that those deals served, at least in part, as payments not to compete.

But plaintiffs went much further, including specific details about each transaction that amply support the inference that Forest's payments are not explained by the value of the generics' goods or services. For instance, the Hetero supply agreement was short and skeletal; unnecessary because of Forest's longstanding and successful relationship with its existing supplier; executed without a competitive bidding process; and especially unusual because Hetero had never manufactured the material before. Compl. ¶¶ 164-68, 170-72. In the Torrent agreement, Forest purchased patents for the active ingredient in Bystolic despite

having previously spent $357 million to acquire what it called "all" Bystolic patents and despite never having indicated that it planned to develop a next-generation Bystolic. *Id.* ¶ 179. And with Glenmark, Forest entered a joint-development agreement related to products in which it had expressed no prior interest; received "largely illusory" rights that it valued at far less than the amount it paid; and committed itself to making full "milestone payments" even if the venture was a failure. *Id.* ¶¶ 188-93. *See also id.* ¶¶ 182, 185 (Forest did not need the Alkem/Indchemie supply agreement and conducted little diligence); ¶¶ 197-98 (Forest had no previous interest in Amerigen's drug development efforts, and the parties only executed an actual agreement upon FTC scrutiny).

In each of these instances, the complaints alleged sufficient facts that, taken as true, support a reasonable inference that these side deals were unusual and lacked the indicia of an independent business transaction. *See AbbVie*, 976 F.3d at 357; *Lipitor*, 868 F.3d at 256-58. Though defendants may ultimately be able to justify these transactions, those justifications are not properly evaluated on a motion to dismiss; they are defendants' burden to prove at step two of the rule of reason.

II. The District Court Contravened *Actavis* And Basic Pleading Standards

When the district court dismissed the complaints, it misapplied *Actavis* and fundamental principles for resolving Rule 12(b)(6) motions. Despite *Actavis*'s

teaching that defendants must justify their reverse payments, 570 U.S. at 156, 58, the court offered its *own* procompetitive justifications for the side deals and faulted plaintiffs for not refuting them in the complaints. The court also found disputed facts against plaintiffs, failed to grant reasonable inferences in plaintiffs' favor, improperly demanded that plaintiffs furnish supporting evidence, and failed to consider the complaint allegations in full context. All of this was improper at the pleading stage.

A. The District Court Wrongly Proffered Its Own Justifications For The Side Deals And Used Them To Discredit The Complaint Allegations

As discussed at pp. 14-18, because defendants have the burden to justify their reverse payments, plaintiffs need not "come up with possible explanations for the reverse payment and then rebut those explanations" to survive a motion to dismiss. *Lipitor*, 868 F.3d at 256; *see also AbbVie*, 976 F.3d at 356 (plaintiffs can meet *prima facie* case without "preempting every possible explanation" for a reverse payment). The district court acknowledged these holdings, First Op. 32, but did not follow them. The court instead faulted plaintiffs for failing to preemptively rebut the court's own procompetitive explanations, and dismissed the complaints on that basis.

For example, the district court found that the Hetero supply agreement "would have value to Forest" because "Forest was dependent on a sole supplier"—

despite plaintiffs' allegations that Forest's existing supplier was adequate and that Forest had no additional need for raw materials. Second Op. 27. The court introduced speculation (nowhere alleged in the complaints) that Forest could have been "simultaneously expressing dissatisfaction" with its current supplier. First Op. 39. The court brushed aside plaintiffs' allegation that Forest's lack of competitive bidding was suspicious, drawing its own contrary "inference" that with "specialized" pharmaceuticals, "there would be no need or opportunity for competitive bidding," and that agreements can be "mutually beneficial [and] pro-competitive" without competing bids. Second Op. 24.

The court repeated these errors when addressing the other side deals. The court rebuffed plaintiffs' allegations that Forest's side deal to buy patents from Torrent was pretextual, holding that plaintiffs had failed to refute the possibility that Forest might need Torrent's patents to "develop and sell a new non-Bystolic" product someday. *Id.* at 30. Worse, the court flatly declared that Forest's product development deal with another generic defendant, Glenmark, provided "substantial value" by giving "Forest a seat at the table and an opportunity to learn from and exploit Glenmark's expertise and know-how." *Id.* at 40. With that assertion, the court rejected plaintiffs' allegations that Forest had no interest in the Glenmark collaboration apart from the patent settlement and valued its rights at only $6 million when it paid $15 million. *Id.* at 38-39.

Requiring plaintiffs to anticipate these hypothesized justifications in their complaints contravened the teachings of *Actavis*. The Supreme Court directly recognized that the mere "possibility" that a reverse payment might be procompetitive "does not justify dismissing the … complaint." *Actavis*, 570 U.S. at 156. Justifications are instead issues for summary judgment and trial, after discovery reveals what (if anything) defendants can support with evidence.

B. The District Court Misapplied The Core Legal Standards For Resolving Motions To Dismiss

When the district court refused to credit the complaints' factual allegations, it defied the basic principles governing Rule 12(b)(6) in at least four ways. The court found facts contrary to the complaint allegations, failed to grant all reasonable inferences in plaintiffs' favor, rejected plaintiffs' well-pleaded allegations due to a lack of supporting evidence, and failed to read the complaint allegations in full context.

1. The court made improper findings of fact

As discussed on pp. 21-22, the district court credited its own procompetitive justifications over the complaint allegations, finding as fact that the side deals provided "value" to Forest. Second Op. 26-27, 32, 34-35, 40-42, 45-46. In the process, the court breached the cardinal rule that courts "must assume the truth of the plaintiff's allegations and avoid resolving factual disputes" when resolving a motion to dismiss. *Oakley v. Dolan*, 980 F.3d 279, 284 (2d Cir. 2020). This Court

corrected a similar "analytical problem[]" in *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162, 189 (2d Cir. 2012), where the lower court found the plaintiff's "view of the events implausible … essentially ma[king] a number of other factual findings." *Id.* at 190 (cleaned up). The value of a contract or asset—along with a party's reasons for entering or acquiring it—are quintessential factual determinations, *see, e.g.*, *Longo v. Shore & Reich, Ltd.*, 25 F.3d 94, 98 (2d Cir. 1994), and the court should have allowed the parties to test plaintiffs' factual allegations in discovery and potentially at trial.

2. The court improperly assessed competing plausible inferences

The district court also failed to "draw[] all reasonable inferences in the plaintiff's favor." *CBF Indústria de Gusa S/A v. AMCI Holdings, Inc.*, 850 F.3d 58, 77 (2d Cir. 2017) (cleaned up). The court rejected various allegations of peculiar or suspicious circumstances surrounding the side deals by holding that the facts "could be entirely consistent with" innocuous behavior. *See, e.g.*, Second Op. 21, 26-27, 30. In the court's view, "conduct that is consistent with and equally explicable by a pro-competitive justification … is not sufficient to state a claim." First Op. 27. This ruling was error. A district court may not dismiss a complaint simply because "an innocuous interpretation of the defendant's conduct may be plausible." *Anderson News*, 680 F.3d at 189-90. It was "not the district court's province to dismiss a plausible complaint because," in the court's view, "it is not

as plausible as the defendant's theory." *Palin v. N.Y. Times Co.*, 940 F.3d 804, 815 (2d Cir. 2019).[10]

The district court reached its mistaken ruling by misreading *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), which stated that plaintiffs cannot plead the existence of an antitrust conspiracy by describing facts that were "just as much in line with a wide swath of rational and competitive business strategy." *Id.* at 554. *See* Second Op. 19. The Supreme Court's observation reflected crucial differences in substantive law that do not apply here. *Twombly* did not address the rule of reason or procompetitive justifications, but dealt with an allegedly per se unlawful antitrust conspiracy stemming from an unwritten agreement. *See Twombly*, 550 U.S. at 550-53. In that context, courts have long "cautioned against drawing an inference of conspiracy from evidence that is *equally consistent* with independent conduct as with illegal conspiracy." *United States v. Apple, Inc.*, 791 F.3d 290, 315 (2d Cir. 2015) (emphasis added).[11]

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[10] The district court's own phrasing suggests that it was reasonable to infer a culpable explanation from the alleged facts. It repeatedly described its preferred innocuous explanations as "equally" or "more" plausible as the suspicious ones. Second Op. 24, 32, 33, 45, 51.

[11] The facts alleged in the complaint in *Twombly* suggested independent action only. *See* 550 U.S. at 566-67. That did not meet the substantive standard for establishing unlawful conspiracy, under which "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice." *Id.* at 556.

Here, by contrast, plaintiffs' allegations met what *Actavis* requires to state a reverse-payment based antitrust claim. The complaints allege that defendants acted pursuant to an express written agreement—which is "clear, direct evidence" of concerted action. *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *8 (N.D. Ga. June 14, 2018). The question is whether the agreements unreasonably restrained trade under the rule of reason. As discussed (at 14-18), plaintiffs have no burden to rule out *justifications* at the pleading stage simply because those might be equally consistent with a culpable inference. *See, e.g.*, *Lipitor*, 868 F.3d at 256. To the contrary, *Twombly* stressed that "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable." 550 U.S. at 556 (cleaned up). Regardless of any reservations the district court held about plaintiffs' ability to prove the violation, the court was required to accept their allegations at the pleading stage.

Indeed, this Court has confirmed that under *Twombly*, "the question … is not whether there is a plausible alternative to the plaintiff's theory." *Anderson News*, 680 F.3d at 189. A court may not "dismiss[] the complaint on the basis of the court's choice among plausible alternatives." *Id.* at 190. Yet that is exactly what the district court did here, when it weighed competing inferences and chose what it described as "[t]he *more plausible* reading of the[] facts." Second Op. 32 (emphasis added); *see also id*. at 24, 33, 45.

3. The court unfairly rejected plaintiffs' claims for lack of supporting evidence

The First Circuit has cautioned that when a court considers the sufficiency of reverse-payment allegations, it may not "convert[] *Twombly*'s mandates into a requirement that antitrust plaintiffs provide evidentiary support or set forth other 'plus factors' to demonstrate … plausibility." *Loestrin*, 814 F.3d at 549 (reversing dismissal). The district court here did just that.

When the district court rejected plaintiffs' charge that Forest's patent side deal with Torrent was pretextual, the court appeared to hold plaintiffs' lack of expert testimony against them. The court distinguished this case from one in which the Commission and its co-plaintiffs defeated *summary judgment* by presenting "expert opinions that [defendant] went outside industry norms and failed to conduct due diligence prior to licensing the Generic Defendants' IP." Second Op. 29 (quoting *King Drug of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 420-21 (E.D. Pa. 2015)). Comparing plaintiffs' allegations unfavorably to *King Drug*, the district court remarked, "Plaintiffs do not allege similar facts here." *Id.* That reasoning was improper, as a district court may not dismiss complaint allegations that require "the aid of … expert testimony" to resolve. *Peter F. Gatto Architecture, LLC v. Simone Dev. Corp.*, 602 F.3d 57, 65 (2d Cir. 2010). Expert analysis will almost certainly be needed to understand the complex, highly technical industry standards for licensing drug patents; but at the pleading stage,

the court was required to accept plaintiffs' allegations detailing how Forest's side deals with Torrent and the other generics contravened industry norms.

The district court also wrongly rebuked plaintiffs for failing to provide "evidence" to support allegations they had pleaded based on "information and belief" and public information. Second Op. 22, 37-38 & 40 n.17. For instance, the court repeatedly discounted plaintiffs' charges that there was no publicly available evidence of Forest engaging in a bid-selection process or showing prior interest in certain collaborations, stating that "[t]he absence of evidence is not evidence of absence." *Id.* at 23, 37-38. But this Court has held that plaintiffs may plead facts based "upon information and belief where the facts are peculiarly within the possession and control of the defendant, or where the belief is based on factual information that makes the inference of culpability plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (cleaned up). This is such a case: As discussed at pp. 15-16, the facts regarding defendants' business needs and contractual negotiations are uniquely within their custody and control and are largely unavailable to plaintiffs before discovery.

4. The court failed to consider the complaint allegations as a whole and in context

Finally, the district court did not follow this Court's directives to "read the allegations of the complaint as a whole in context," *Cohen v. S.A.C. Trading Corp.*, 711 F.3d 353, 360 (2d Cir. 2013), and consider "the full factual picture" before

granting a motion to dismiss, *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 430 (2d Cir. 2011). These requirements are especially critical in antitrust cases, where courts "must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Comms., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004).

In this case, the district court lost sight of the entire factual picture, which showed a viable *Actavis* claim. The court purportedly accepted plaintiffs' allegations that Forest induced *six separate generic companies* to agree not to launch rival drugs for the next eight years, and made lucrative reverse payments to at least five of those companies as part of "related" "side deals" executed at the same time. *Supra* pp. 10, 18-19. Taking these allegations as true, a plausible inference would be that the side-deal payments served, at least in part, as consideration for the generics' simultaneous pledges not to compete. And yet the court trained its sights exclusively on features of individual side deals without explaining why dismissal was appropriate given this overall context.

The district court compounded this error by holding that certain allegations about each side deal were "alone" insufficient, without considering the totality of circumstances that made each deal inconsistent with a normal business arrangement. *See* First Op. 34-57. For example, plaintiffs allege a panoply of reasons why the Forest-Hetero supply deal was peculiar, including that Forest

already had sufficient supply; did not follow the normal industry practice of getting competitive bids; entered a cursory agreement lacking the normal details; and chose Hetero even though Hetero had never manufactured the materials before. Compl. ¶¶ 165, 168, 170-72. Rather than considering whether a reasonable factfinder could infer from this combination of alleged unusual features—viewed in the context of a pattern of other similarly unusual agreements—that the deal was a disguised reverse payment, the district court reviewed and rejected each allegation as insufficient in isolation.[12]

Such a siloed analysis stands plainly in conflict with Supreme Court precedent. In the antitrust context, the Supreme Court has admonished that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-99 (1962). This Court should not let these errors stand.

CONCLUSION

The district court's judgment dismissing the complaints should be reversed.

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[12] *See*, *e.g.*, First Op. 39 ("[T]he allegation of sufficient existing supply, *alone*, does not make the inference of culpability plausible." (emphasis added)); Second Op. 26-27 ("*The mere fact* that the Final Term Sheet was a preliminary agreement . . . is insufficient to raise a reasonable inference that the agreement itself was not a bona fide transaction." (emphasis added)).

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Local Rules 29.1(c) and 32.1(a)(4)(A) because it contains 6,991 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), and that it complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it was prepared using Microsoft Word in 14 point Times New Roman type.

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CERTIFICATE OF SERVICE

I certify that on June 20, 2023, I served the foregoing on counsel of record using the Court's electronic case filing system. All counsel of record are registered ECF filers.

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