No. 23-410-cv(L)

No. 23-418-cv(CON), No. 23-420-cv(CON), No. 23-423-cv(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 (Honorable Lewis J. Liman)

BRIEF FOR DEFENDANTS-APPELLEES

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(Counsel continued on inside covers)

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.,

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CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Defendants-Appellees make the following disclosures:

ABBVIE INC., ALLERGAN INC., ALLERGAN SALES LLC, ALLERGAN USA, INC., FOREST LABORATORIES INC., FOREST LABORATORIES HOLDINGS LTD., FOREST LABORATORIES IRELAND, LTD., AND WATSON PHARMACEUTICALS INC. (LATER KNOWN AS ACTAVIS, INC.)

The undersigned counsel for Defendants-Appellees AbbVie Inc., Allergan Inc., Allergan Sales LLC, Allergan USA, Inc., Forest Laboratories Inc., Forest Laboratories Holdings Ltd., Forest Laboratories Ireland, LTD., and Watson Pharmaceuticals, Inc. (later known as Actavis, Inc.) hereby certify that:

Watson Pharmaceuticals, Inc. and Actavis, Inc. no longer exist due to corporate mergers.

Forest Laboratories Inc. became Forest Laboratories, LLC, a limited liability company. Forest Laboratories, LLC was merged into Allergan Sales, LLC. Allergan Sales, LLC, is a direct or indirect wholly owned subsidiary of AbbVie Inc.

Allergan USA, Inc., Allergan, Inc., Forest Laboratories Ireland, Ltd., and Forest Laboratories Holdings Limited also are all direct or indirect wholly owned subsidiaries of AbbVie Inc.

AbbVie Inc. is a publicly traded Delaware corporation, and no parent corporation or publicly traded corporation owns 10% or more of AbbVie Inc.'s stock.

HETERO LABS LTD., HETERO DRUGS LTD., AND HETERO USA INC.

The undersigned counsel for Defendants-Appellees Hetero Labs Ltd., Hetero Drugs Ltd., and Hetero USA Inc. hereby certifies that no parent corporation or publicly traded corporation owns 10% or more of Hetero Labs Ltd. or Hetero Drugs Ltd. Hetero Labs Ltd. and Hetero Drugs Ltd. are parent corporations of Hetero USA, Inc., which each own a 50% share of Hetero USA, Inc.

TORRENT PHARMA, INC.

The undersigned counsel for Defendant-Appellee Torrent Pharma, Inc. hereby certify that: (1) Torrent Pharma, Inc. ("Torrent") is a nongovernmental corporate party; (2) Torrent is a wholly owned subsidiary of Torrent Pharmaceuticals Ltd., which is a wholly owned subsidiary of Torrent Private Ltd.; and (3) Torrent is incorporated under the laws of Delaware and has its principal place of business in New Jersey.

INDCHEMIE HEALTH SPECIALTIES PRIVATE LTD., ALKEM LABORATORIES LTD., ASCEND LABORATORIES LLC

The undersigned counsel for Defendants-Appellees Indchemie Health Specialties Private Ltd., Alkem Laboratories Ltd., and Ascend Laboratories LLC hereby certify that Indchemie Health Specialties Private Ltd. is a subsidiary of Alkem Laboratories Ltd. Alkem Laboratories Ltd. owns 10% or more of Indchemie Health Specialties Private Ltd.'s stock.

Ascend Laboratories LLC's parent is ThePharmaNetwork, LLC, and the parent corporation for ThePharmaNetwork, LLC is Alkem Laboratories Ltd.

Alkem Laboratories Ltd. has no parent corporation and no publicly held corporation owns 10% or more of Alkem Laboratories Ltd.'s stock.

GLENMARK GENERICS, INC., USA N/K/A GLENMARK PHARMACEUTICALS INC., GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS S.A., AND GLENMARK PHARMACEUTICALS LTD.

The undersigned counsel for Defendants-Appellees Glenmark Generics Inc., USA, Glenmark Generics Ltd., Glenmark Pharmaceuticals S.A., and Glenmark Pharmaceuticals Ltd. hereby certify that:

Glenmark Generics Inc., USA is now known as Glenmark Pharmaceuticals Inc., USA.

Glenmark Generics Ltd. is now known as Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals S.A. is now known as Ichnos Sciences S.A.

Glenmark Pharmaceuticals Inc., USA and Ichnos Sciences S.A. are subsidiaries of Glenmark Pharmaceuticals Ltd., a corporation duly formed under the commercial code of India with shares listed on the Bombay Stock Exchange and the National Stock Exchange. No other publicly held corporation owns 10% or more interest in Glenmark Pharmaceuticals Inc., USA, Ichnos Sciences S.A., or Glenmark Pharmaceuticals Ltd.

ANI PHARMACEUTICALS, INC.

The undersigned counsel for Defendant-Appellee ANI Pharmaceuticals, Inc. hereby certify that ANI Pharmaceuticals, Inc. is a Delaware corporation the shares of which are publicly traded on the NASDAQ stock exchange under the ticker symbol ANIP. ANI Pharmaceuticals, Inc. does not have a parent company. ANI Pharmaceuticals, Inc. further discloses that, as of January 2023, BlackRock, Inc., a public company the shares of which are publicly traded on the New York Stock Exchange under the ticker symbol BLK, held 11.4% of ANI Pharmaceuticals, Inc.'s stock.

AMERIGEN PHARMACEUTICALS LTD. AND AMERIGEN PHARMACEUTICALS INC.

The undersigned counsel for Defendants-Appellees Amerigen Pharmaceuticals Ltd. and Amerigen Pharmaceuticals Inc. hereby certifies that Amerigen Pharmaceuticals Inc., which has been wound up, was a subsidiary of Amerigen Pharmaceuticals Ltd., and that Amerigen Pharmaceuticals Ltd. has no parent corporation and no publicly-held corporation owns 10% or more of Amerigen Pharmaceuticals Ltd.'s stock.

WATSON PHARMA, INC. (N/K/A ACTAVIS PHARMA, INC.), WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (DE) (N/K/A ACTAVIS LABORATORIES UT, INC.), WATSON LABORATORIES, INC. (NY) (LATER KNOWN AS ACTAVIS LABORATORIES NY, INC.), WATSON LABORATORIES, INC. (CT), TEVA PHARMACEUTICAL INDUSTRIES LTD., AND TEVA PHARMACEUTICALS USA, INC.

The undersigned counsel for Defendants-Appellees Watson Pharma, Inc. (n/k/a Actavis Pharma, Inc.), Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE) (n/k/a Actavis Laboratories UT, Inc.), Watson Laboratories, Inc. (NY) (later known as Actavis Laboratories NY, Inc.), Watson Laboratories, Inc. (CT), Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. hereby certify that:

Teva Pharmaceuticals USA, Inc. ("Teva USA") is an indirectly wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which is a publicly traded company. Teva Ltd. is the only publicly traded company that owns 10% or more of the stock of Teva USA.

Watson Pharma, Inc. (n/k/a Actavis Pharma, Inc.), Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE) (n/k/a Actavis Laboratories UT, Inc.), and Watson Laboratories, Inc. (CT) (together, the "Watson Entities") are also indirectly wholly-owned subsidiaries of Teva Ltd. Teva Ltd. is the only publicly traded company that owns 10% or more of the stock of the Watson Entities.

Watson Laboratories, Inc. (NY) later became known as Actavis Laboratories NY, Inc. In 2019, Teva Ltd. sold Watson Laboratories, Inc. (NY), and this company is no longer affiliated with Teva Ltd.

Teva Ltd. has no parent company and no publicly traded company owns 10% or more of the stock of Teva Ltd.

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PRELIMINARY STATEMENT

Two rules compel dismissal. First, this Court regularly affirms dismissals under Rule 12 of the Federal Rules of Civil Procedure when documents incorporated by reference into the complaint belie the complaint's allegations and the plaintiff's hoped-for inferences. *See* Argument I *infra* 22-23 (collecting cases).

This rule applies with particular force here because the agreements that Appellants challenge as antitrust violations are fully executed contracts. That is, the purported illegal agreements here allegedly reside within the four corners of written contracts, which Appellants received in early discovery well before filing their operative amended complaints. *See* S.A.-0068 n.5.

That the alleged illegal agreements here are memorialized in written contracts is a critical distinction from the cases on which Appellants rely:

> Although the district court in the present case . . . faulted Anderson's Complaint for not contain[ing] allegations of direct evidence of a conspiracy, ***conspiracies are rarely evidenced by explicit agreements***, but nearly always must be proven through inferences that may fairly be drawn from the behavior of the alleged conspirators[.]

Anderson News, LLC v. Am. Media, Inc., 680 F.3d 162, 183 (2d Cir. 2012) (cleaned up) (emphasis added); *see also* J.A.-2030:4–31:1 (vol. 9) (Appellees addressing *Anderson News*'s distinction at the district court's 3.5-hour motion-to-dismiss hearing: "*Anderson News* was all backroom meetings and [or]al[] agreements and no written contracts subject to objective valuation. That's a very different situation

than here, your Honor. . . . No written agreements in *Anderson News*. Lots of written agreements here. . . . I must have said the word 'exhibit' about 15 times this morning. I didn't hear it once from plaintiffs. They are not addressing the contracts in this case, your Honor, that their allegations have put at issue.").

The operative complaints largely ignore the provisions of the written agreements that Appellants challenge (as does Appellants' brief). But this Court's precedents require courts applying Rule 12 to measure allegations and proposed inferences against documents incorporated into the complaint. The district court correctly applied that precedent and dismissed because Appellants' allegations and proposed inferences contradict the express terms of the written agreements at issue. The same result must follow here.

The second rule compelling dismissal is the Supreme Court's decision in *Actavis* that an antitrust plaintiff challenging a patent-litigation settlement state a claim by alleging "a reverse payment, where large and unjustified . . . ." 570 U.S. at 158. *Actavis* held that the complaint there met both the "large and unjustified" requirements—but *not* merely by alleging that the contemporaneous business transactions "had little value," as Appellants suggest, *e.g.*, Br. 22. In fact, the words "had little value" do *not* appear in the *Actavis* complaint at all; that was only the Court's shorthand characterization of the allegations in the factual-background section. 570 U.S. at 145.

Rather, the complaint in *Actavis* provided the Court sufficient detail to assess that the plaintiff had pleaded adequately an "implicit net payment" for the business transactions at issue by alleging that the brand company had paid the generic companies ***667%–1,000% more than the brand company previously had paid for the same or similar services***. *See* 570 U.S. at 145 (citing seven paragraphs in the complaint detailing total payments of at least $243 million for services for which the brand company previously had paid as little as one-tenth that amount); *id.* at 151 (referencing an "implicit net payment").

Those factual allegations in *Actavis* enabled the Court to determine that the plaintiff had alleged adequately a "payment in return for staying out of the market," *id.* at 154, rather than "fair value for services," *id.* at 156. Contrary to Appellants' contention that a "payment for fair value might still represent an improper *quid pro quo* for an *agreement* to delay generic entry," Br. 45, *Actavis* expressly held:

> 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.

570 U.S. at 156 (emphasis added).

This point is central to this appeal and bears emphasis: Appellants' premise is that *Actavis* does *not* require plaintiffs to allege that a reverse payment is both "large and unjustified," *e.g.*, Br. 1, 8, 9, 12, 22, etc., because, according to

Appellants, even a fairly valued business transaction contemporaneous with a patent settlement can support a claim under *Actavis*. That misstates the law.[1]

Actavis unequivocally holds that a plaintiff must first allege the factual predicate for a "large and unjustified" payment—e.g., the overpayment of 667%–1,000% alleged there—to subject the transaction to antitrust scrutiny and trigger the defendant's subsequent burden to defend and potentially justify the transaction: "In sum, a reverse payment, where large and unjustified can bring with it the risk of significant anticompetitive effects; one who makes *such a payment* may be unable to explain and justify it[.]" 570 U.S. at 158 (emphasis added).

For further context, when *Actavis* held that an antitrust claim can be brought concerning "large and unjustified" reverse payments, the Court resolved a split between circuits (including this one) that had accorded "near-automatic antitrust immunity to reverse payment settlements" and the Third Circuit, which adopted the FTC's proposed "quick look" rule deeming reverse-payment settlements presumptively unlawful. *Id.* at 158-59; *cf. In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *abrogated by Actavis*.

[1] As discussed below, in at least some instances Appellants do not plausibly allege that a challenged agreement conveyed a large reverse payment *at all*, much less one that is both large and unjustified. *See infra* 57.

Actavis thus rejected the extremes of either presumption and charted a middle course. *See* 570 U.S. at 159 ("[T]he FTC must prove its case as in other rule-of-reason cases."). In rendering alleged "large and unjustified" reverse payments subject to ordinary, rule-of-reason antitrust scrutiny, *Actavis* did not *sub silentio* exempt such claims from the Court's previously elucidated principles in *Twombly* and *Iqbal*.

Every circuit that has applied *Actavis* under Rule 12 accordingly agrees with the "large and unjustified" pleading requirement. *See* Argument II.B *infra* 30-32.

Taken together, then, the rules of decision here are that: (i) to state a claim under *Actavis*, a plaintiff must adequately allege a factual basis for a "large and unjustified" reverse payment; and (ii) Rule 12 requires that Appellants' allegations and proposed inferences be measured against the provisions of the challenged contracts, which Appellees produced in early discovery and are incorporated by reference into the operative amended complaints.

* * *

This case appears to be the first time that this Court will apply *Actavis* to a patent-litigation settlement. In *In re Actos End-Payor Antitrust Litigation*, 848 F.3d 89 (2d Cir. 2017), this Court addressed the Rule 12 dismissal of an antitrust complaint concerning a patent-litigation settlement, but the plaintiff did not appeal the dismissal of its reverse-payment claim, so this Court did not apply *Actavis*.

In *1-800-CONTACTS, Inc. v. FTC*, 1 F.4th 102 (2d Cir. 2021) (per curiam), this Court applied *Actavis* to the FTC's administrative condemnation of multi-party trademark settlements. This Court observed: "When the restraint at issue in an antitrust action implicates IP rights, *Actavis* directs us to consider the policy goals of the relevant IP law." *Id.* at 121-22. The FTC brought its administrative action in 2016, three years post-*Actavis*, and nonetheless condemned the trademark settlements and contemporaneous business transactions at issue under the "quick look" approach of presumptive illegality that the agency had advocated for unsuccessfully in *Actavis*. *See id.* at 115-16.

This Court's decision in *1-800-CONTACTS* rejected the FTC's mode of antitrust analysis and vacated the agency's decision. As in *Actavis*, this Court held that ordinary rule-of-reason principles govern:

> A plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. *After a prima facie case of anticompetitive conduct has been established*, the burden shifts to the defendant to proffer procompetitive justifications for the agreement.

Id. at 114 (emphasis added).

Rather than remanding the FTC's "quick look" decision for reconsideration under the rule of reason, this Court evaluated the trademark settlements and contemporaneous business agreements firsthand and dismissed the FTC's administrative complaint, holding that the agreements were lawful. *Id.* at 122.

In doing so, this Court chided the FTC for second-guessing the IP rights underlying the settlements. *Compare id.* at 120 ("The Commission, however, decided that the trademark claims that led to the Challenged Agreements were likely meritless."), *with, e.g.*, Br. 9 ("Plaintiffs alleged that Forest's '040 Patent was weak and that Forest could not prevail in the patent litigation.").

Neither Appellants nor the FTC mention *1-800-CONTACTS*.

COUNTER-STATEMENT OF JURISDICTION

Appellants contend that this appeal concerns *both* the district court's initial dismissal without prejudice (S.A.-0065) and final order of dismissal with prejudice (S.A.-0119). *E.g.*, Br. 2. But because Appellants amended their complaints in response to the initial dismissal, only the currently operative complaints and the district court's dismissal with prejudice are at issue. *See Ramirez v. Collier*, 142 S. Ct. 1264, 1276 (2022) ("As a general rule, when a plaintiff files an amended complaint, the amended complaint supersedes the original, the latter being treated thereafter as non-existent."); *Dluhos v. Floating & Abandoned Vessel*, 162 F.3d 63, 68 (2d Cir. 1998) (same).

Having spent the candle to amend its complaint, why would a plaintiff worry about a concededly less-definite, superseded complaint? As detailed in the Statement of the Case, Appellants are among the most active, recurring antitrust plaintiffs in the country and they apparently have bigger fish to fry than this case.

STATEMENT OF THE ISSUES PRESENTED

1. The answer to Appellants' first issue presented (Br. 3) is no. The answer is no because Appellants' "where" clause revealingly removes the "unjustified" component of *Actavis*'s pleading requirement. Nothing in *Actavis* supports Appellants' suggestion of a "need"-based test for a business transaction contemporaneous with a patent settlement. *Actavis* expressly preserves parties' ability to settle patent cases with "traditional settlement considerations, such as avoided litigation costs or fair value for services[.]" 570 U.S. at 156.

Properly stated, the first issue presented is whether *Actavis* requires a plaintiff to allege an adequate factual basis for a plausible "large and unjustified" reverse payment—unlike Appellants' contention that alleging a "large" business transaction contemporaneous with settlement suffices.

2. On de novo review, the second issue presented is whether Appellants' formulaic, verbatim allegations that each business transaction here "exceeded the fair value of any products delivered or services rendered" is sufficient to state a claim under *Actavis* concerning the detailed, written contracts that Appellants challenge and incorporate by reference into their complaints.

STATEMENT OF THE CASE

I. APPELLANTS, THEIR ASSIGNORS, AND THEIR RECURRING ANTITRUST SUITS

Appellants—Direct-Purchaser Plaintiffs (wholesalers), End-Payor Plaintiffs (insurers), and Retailer Plaintiffs (pharmacies)—began filing their class-action and individual complaints in 2020. *See* Br. 5 n.2 (stipulating there are no analytical differences in the operative complaints).

Appellants are among the most recurring and sophisticated antitrust plaintiffs in the United States. For example, for antitrust plaintiffs in the federal courts in 2018-2022, Appellants KPH and Kroger were tied for the third most frequent plaintiff, coming behind only the DOJ and California; Appellants Walgreen, Albertsons, CVS, and the City Council of Baltimore are all in the top ten.[2]

Additionally, several Appellants lack independent standing and are proceeding merely as assignees. J.A.-1485 ¶32 (vol. 7) (alleging KPH is proceeding as a partial assignee of direct purchaser McKesson); J.A.-1258 ¶¶29-32, J.A.-1372 ¶¶29-30 (vol. 6) (alleging Retailers are proceeding as partial assignees of direct purchasers McKesson, AmerisourceBergen, and Cardinal). Appellants' assignors are all publicly traded national wholesalers with billions of dollars in

[2] Ron Porter, *Antitrust Litigation Report 2023*, LEX MACHINA 16 fig. 12 (Apr. 2023), *reprinted as fig. 3 at* law360.com/articles/1598923.

annual revenue that routinely engage in claim splitting and seek to recover alleged antitrust damages as absent class members. *See, e.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, 7 F.4th 227, 233 (4th Cir. 2021); *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 259 (3d Cir. 2016).

II. THE PTO GRANTED TWO PATENTS COVERING BYSTOLIC AND CONFIRMED VALIDITY DURING REEXAMINATION.

Bystolic® is one of many branded and generic medicines approved by the FDA for the treatment of high blood pressure. *See* FDA, *High Blood Pressure Medicines* (2021), fda.gov/media/147354/download. Bystolic is a beta-blocker treatment that contains the active pharmaceutical ingredient ("API") nebivolol hydrochloride. J.A.-1475-76 ¶1 (vol. 7).

The U.S. Patent and Trademark Office ("PTO") granted two patents covering Bystolic: U.S. Patent Nos. 5,759,580 and 6,545,040. J.A.-1514 ¶123 (vol. 7). As Appellants concede, "the '040 Patent was subjected to reexamination proceedings and a reexamination certificate issued in 2009." J.A.-1519 ¶138 (vol. 7). That reexamination resulted in the PTO confirming the patentability of all claims in the '040 Patent. *See* Ex Parte Reexamination Certificate (issued Feb. 17, 2009), image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/6545040. As a result, the presumption of patent validity, which can be overcome only by "clear and convincing evidence," *Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91, 97-99 (2011), became even stronger given the PTO's ruling, *see Shire, LLC v. Amneal Pharms.,*

LLC, 802 F.3d 1301, 1307 (Fed. Cir. 2015) (describing "added burden of overcoming the deference" due to PTO).

The '580 Patent expired on June 2, 2015, and the '040 Patent expired on December 17, 2021, thus the PTO had confirmed the validity of Forest's latest-expiring Bystolic patent. *See* J.A.-1514-15 ¶¶123-24 (vol. 7). Furthermore, Forest received five years of marketing exclusivity because Bystolic's active ingredient qualified as a New Chemical Entity ("NCE") under Hatch-Waxman. J.A.-1505-06 ¶100 (vol. 7). As an FDA-regulatory reward for Forest's NCE innovation, ANDAs with Paragraph-IV certifications were impermissible during the first four years of that exclusivity. *Id.*

III. THE GENERICS AND A THIRD PARTY INDEPENDENTLY BROUGHT UNSUCCESSFUL PATENT CHALLENGES AGAINST BYSTOLIC.

In February 2012, Forest received Paragraph-IV notices from the seven Generics that filed ANDAs for Bystolic. J.A.-1520-21-¶143-(vol.-7). All seven Generics were "first filers" and eligible to share 180-days of exclusivity. J.A.-1519 ¶¶139-40 (vol. 7). According to the FDA, shared first-filer exclusivity is commonplace when, as here, "the expiration of 4 years of a 5-year [NCE] exclusivity period under section 505(j)(5)(D)(ii) permits submission of ANDAs containing a paragraph IV certification as of a specific date, and multiple applicants vie to be first to make such a submission." FDA, *Guidance for Industry: 180-Day Exclusivity*

When Multiple ANDAs Are Submitted on the Same Day 4 (2003), fda.gov/media/71304/download; *see also* J.A.-1507 ¶105 n.74 (vol. 7) (citing FDA guidance describing shared first-filer scenarios).

In other words, each of the Generics independently had a set, four-year runway to file its ANDA on the first legally permissible date, which is why they ultimately all filed on the same day and shared first-filer status.

Forest timely filed patent-infringement lawsuits against the Generics, which were consolidated in the Northern District of Illinois. J.A.-1521-22 ¶¶145-47 (vol. 7). The lawsuits triggered automatic stays under Hatch-Waxman, during which the FDA could not grant final approval of any Bystolic ANDA until June 18, 2015, unless there was an earlier favorable decision for that Generic on non-infringement, or a decision invalidating the patent. J.A.-1477 ¶4, J.A.-1505-06 ¶100 (vol. 7) (NCE extension of 30-month stay). The patent litigation focused on Forest's '040 Patent because several Generics did *not* challenge Forest's '580 patent. *See* J.A.-1517-18 ¶¶130-32 (vol. 7).

Altogether, once consolidated, the patent litigation lasted 18 months from June 2012 to December 2013. *In re Nebivolol ('040) Patent Litig.*, No. 12-cv-5026 (N.D. Ill.). During that time, the Generics had no degree of success whatsoever in pressing either their invalidity or non-infringement arguments. *See id.* Of the seven Generics, only Alkem and Indchemie moved for summary judgment, which the

district court denied. *Id.*, ECF 57. There was no other substantive ruling in the case.

Starting in October 2012, shortly after the summary-judgment denial in August 2012, the Generics began to settle the patent litigation—years before the statutorily extended 30-month stay and unchallenged '580 Patent would expire, and years before any of the Generics could have received final FDA approval. J.A.-1476-78 ¶¶3-5 (vol. 7).

After the settlements, in 2016, a third party filed a petition challenging the validity of Forest's '040 Patent, but the Patent and Trademark Trial and Appeal Board ("PTAB") dismissed the petition as not likely to succeed on any claim. *Lower Drug Prices for Consumers, LLC v. Forest Lab's Holdings Ltd.*, No. 16-379, 2016 WL 5231792 (P.T.A.B. July 1, 2016), *reh'g denied*, 2016 WL 6958131 (P.T.A.B. Oct. 19, 2016). Although five years remained on the '040 Patent, Appellants do not allege that any other party ever challenged Forest's patent, despite Bystolic "generating nearly $1 billion in annual sales." Br. 6.[3]

Appellants omit these facts about the patent litigation, the PTO reexamination confirming the validity of Forest's latest-expiring patent, and the unsuccessful

[3] Per FTC data, it is worthwhile for generic firms to initiate Paragraph-IV challenges even when the odds of success are only 3%. Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, Competition Policy Int'l (Sept. 2012), http://bit.ly/1I8Uktd.

PTAB challenge. *See* Br. 9-11. Appellants simply reassert the same arguments made by the Generics in the patent litigation, which failed in the patent case, were rejected by the PTO, and deemed unlikely to succeed by the PTAB. J.A.-1523-24 ¶¶150-51 (vol. 7).

All told, there is not now—nor can there ever be—*any* factual record from the underlying patent litigation or ancillary patent proceedings on which Appellants could base a plausible allegation that the "'040 Patent was weak and that Forest could not prevail in the patent litigation." Br. 9.[4]

By contrast, the patent litigation in *Actavis*, for example, proceeded much differently. At the time of settlement in *Actavis*, fact and expert discovery was complete, and summary-judgment "motions were fully briefed and ready for decision when the statutorily imposed 30-month stay on the FDA's approval process for [the first-filer generic's] ANDA ended in January 2006." *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1304 (11th Cir. 2012), *rev'd on other grounds sub nom. Actavis*.

As the complaint in *Actavis* alleged, with the summary-judgment and *Markman* hearing approaching, and the first-filer having already received final FDA

[4] As the district court observed, Appellants' attempt to label the '040 Patent "narrow" is an asserted legal conclusion that cannot be credited as a factual allegation. S.A.-0095 n.15 (citing *Hamilton v. Westchester Cnty.*, 3 F.4th 86, 90 (2d Cir. 2021)).

approval, the first-filer represented "a near-term threat" and could have launched "at-risk" before a final decision from the district court. Sec. Am. Compl. ¶¶52-53, *Actavis*, No. 1:09-cv-955 (N.D. Ga. May 28, 2009), ECF 114; *see generally, e.g.*, *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 743 (E.D. Pa. 2014) (alleging patent holder settled "the day before the thirty-month stay was set to expire" because it faced an "impending at-risk launch").

Actavis thus involved a meaningfully different patent litigation than this case because, here, the settlements occurred years before any potential generic launch and after Forest had prevailed in the only substantive ruling in the patent litigation.

Indeed, unlike this case, reverse-payment cases typically allege facts attesting to the weakness of the patents in the underlying patent litigation. *See, e.g.*, *Tamoxifen*, 466 F.3d at 190 (2d Cir. 2006) (observing settlement "was contingent on obtaining a vacatur of the judgment of the district court that had heard the infringement action holding the patent to be invalid"); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 247 (3d Cir. 2017) (noting settlement "vacate[d] the *Markman* ruling" because patent holder "feared that it would lose" and a "loss would have enabled other generic" challenges); *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017) (observing "patent in question has been found to be invalid and non-infringed"); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 766 (E.D. Pa. 2015) (noting generic won summary judgment in patent case); *United Food & Com.*

Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1063 (N.D. Cal. 2014) (observing "evidence at trial was overwhelmingly in favor of [the generic]"); *see also FTC v. AbbVie Inc.*, 976 F.3d 327, 338 (3d Cir. 2020) (alleging patent holder pursued sham patent litigation before settling with a reverse payment).

IV. THE EARLY-ENTRY SETTLEMENTS HERE REFLECT TRADITIONAL SETTLEMENT CONSIDERATIONS CONSISTENT WITH *ACTAVIS*.

Under the patent settlements here, Forest and each Generic independently agreed to settle on terms enabling generic entry on September 17, 2021, three months prior to patent expiry, unless another generic entered the market earlier, in which case the September 17, 2021 entry date would be accelerated to that earlier entry date. J.A.-1482-83 ¶21 (vol. 7). Forest made small payments to some Generics at or well below $2 million for "avoided litigation costs" or attorneys' fees. J.A.-1528-43 ¶¶163 176, 181, 188, 195, 200 (vol. 7). These payments are well within the FTC's $7 million safe harbor. *See, e.g.*, *FTC v. Cephalon, Inc.*, No. 08-2141, 2015 WL 4931442, at *2 (E.D. Pa. June 17, 2015) (excluding from definition of "payment" any "compensation for saved future litigation expenses not to exceed a maximum limit, which is initially set at seven million dollars" per ANDA filer).

Rather than challenging the early-entry terms or payments for avoided-litigation costs, Appellants challenge business agreements that Forest entered into

with some Generics and non-party Moksha8. J.A.-1528-49 ¶¶163-220 (vol. 7).

Those business transactions involve:

- Hetero supplying the API for Bystolic to Forest at a price that was at least 15% lower than Forest's existing supplier's price, J.A.-0666 §4.3 (vol. 3);

- Torrent selling 10 patents to Forest, enabling Forest to develop a new nebivolol product called Byvalson during the nine years that remained before generic entry for Bystolic, J.A.-1532-34 ¶¶176-80 (vol. 7);

- Alkem supplying Forest with finished-dosage forms of Bystolic and Byvalson (i.e., the completed tablets rather than an ingredient), subject to specific per-tablet pricing caps of "no higher than" 2.375¢ and 4.75¢ and a "competitive" market-pricing clause, J.A.-0855 (vol. 4);

- Glenmark partnering with Forest to develop novel mPGES-1 inhibitors, subject to various milestone requirements and Glenmark's right to shop commercialization rights for mPGES-1 to other companies, provided the terms are not "materially more favorable to such Third Party than the terms and conditions last offered by Glenmark to Forest," J.A.-1540 ¶191(c) (vol. 7); J.A.-1013 Art. 6.4(b)(5) (vol. 5);

- Amerigen partnering with Forest to invest in certain U.S. drug development and Latin American commercialization efforts, provided that if Amerigen fails to commercialize at least one of the "US products" within five years, then Forest recoups 100% of all milestone payments (or a 50% payback if some products succeed but others fail), and if they do succeed, Forest earns 20% of gross margin, J.A.-1096-97 Arts. 5.2(a)(ii), 5.2(b)(ii), J.A.-1113, 1117-18 (vol. 5); and

- Forest providing a loan of approximately $7 million to Moksha8, a Brazilian pharmaceutical company with which Forest and Watson had independent business dealings predating, and unrelated to, the patent litigation. Moksha8 and Watson also entered into a termination and release agreement, with Watson providing $4 million in consideration to Moksha8 for mutual releases. J.A.-1546-47 ¶¶214-15 (vol. 7). Appellants allege these agreements are connected but concede that they "cannot tell precisely how Forest used the transaction with Moksha8 to transfer this payment to Watson," J.A.-1547 ¶215 (vol. 7). As a result, the district court concluded that Appellants did not

plausibly allege the existence of *any* payment to Watson, much less one that is both large and unjustified. *See* Br. 23.[5]

V. THE FTC INVESTIGATED THE AGREEMENTS AT ISSUE AND TOOK NO ACTION.

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Forest and the Generics timely filed each of the patent settlements and business agreements with the FTC and DOJ. *See* J.A.-1165, J.A.-1174 (vol. 5). Moreover, under the law, the companies had an ongoing duty to disclose any additional related agreements.[6] The FTC investigated the transactions but did not take any action. J.A.-1542 ¶198 (vol. 7).

SUMMARY OF THE ARGUMENT

The district court faithfully applied *Twombly*, *Iqbal*, *Actavis*, and this Court's precedents under Rule 12 in holding that Appellants failed to allege adequately any plausible large and unjustified payment. For example, as the district court held, the plain terms of the challenged agreements contradict Appellants' brazen mischaracterization of three disjunctive criteria in a merger-disclosure document to

[5] The complaints improperly group Appellees together and fail to offer individual facts to even allege a claim against several of the Appellees that were not parties to any of the settlements or business transactions, such as ANI Pharmaceuticals, Inc., Ascend Laboratories, LLC, Allergan, Inc., Allergan USA, Inc., and AbbVie Inc.

[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, §1112(c)(2), Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2461.

suggest that each business agreement was worth at least $15 million dollars. *See infra* 38.

In measuring the complaint against the terms of the challenged contracts, Appellants contend that the district court improperly weighed competing inferences under *Anderson News*. But, as detailed herein, Appellants' contention ignores that *Anderson News* did *not* involve "explicit agreements," 680 F.3d at 183.

Here, the explicit terms of the challenged agreements preclude any plausible inference of a "large and unjustified" payment—such as where the district court held that the Hetero API supply agreement, on its face, definitively constituted a cheaper alternative than Forest's existing supplier. *See infra* 24-25. Because Appellants allege no facts suggesting that Forest made payments beyond the terms of the challenged agreements, Rule 12 required the district court (and requires this Court) to determine whether the terms of those agreements support a plausible inference of large and unjustified payments under *Actavis*. *See infra* 22-25.

While reaching those dispositive conclusions based directly on the terms of the challenged agreements, the district court's 53-page opinion carefully addressed *all* of Appellants' contentions and proposed inferences, however tangential to the court's holdings driven by the agreement terms. None of Appellants' sought-after peripheral inferences could alter the conclusions under Rule 12 dictated by *Actavis*

on whether the agreements at issue plausibly support inferences of large and unjustified payments. *See infra* 36-37.

Implicitly acknowledging that they have *not* alleged plausible large and unjustified payments, Appellants seek to sidestep or reformulate *Actavis*'s pleading requirement. For example, Appellants posit throughout that any business transaction nominally worth more than a patent holder's avoided-litigation expenses suffices to state a claim. But, in fact, *Actavis* addressed allegations of ten-fold overpayments in the hundreds of millions of dollars and referred expressly to an alleged reverse payment's "*scale* in relation to the payor's anticipated future litigation costs," 570 U.S. at 159 (emphasis added). In context, *Actavis* plainly referred to a magnitudinal comparison rather than Appellants' designed-to-fail test, which would subject virtually all business transactions contemporaneous with settlement to follow-on antitrust litigation and burdensome discovery.

Moreover, Appellants' exclusive consideration of a business transaction's nominal compensation terms disregards *Actavis*'s reference to "an implicit net payment" and express statement that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon . . . its *independence* from other services for which it might represent payment," 570 U.S. at 151, 159 (emphasis added). These statements in *Actavis*, and the ten-fold overpayments alleged there

that triggered such observations, render Appellants' sole focus on nominal payment terms fanciful.

Most fundamentally, Appellants disclaim any obligation to plead facts that plausibly meet *Actavis*'s "unjustified" prong: "Allegations of large payments by a brand to a competitor to settle patent litigation—as Plaintiffs make here—are sufficient to state a plausible antitrust claim." Br. 37. Appellants ignore that *Actavis* expressly requires a "large and unjustified," 570 U.S. at 158, reverse payment to state a claim, and that every circuit to address the issue under Rule 12 agrees with this conjunctive pleading requirement. Instead, Appellants suggest various reformulated pleading standards such as whether the patent holder "needed" a business transaction or whether even an indisputably fair-value transaction nonetheless "induced" the settlement—none of which derive from *Actavis* or could ever reasonably be administered by courts under Rule 12. *See infra* 33-34 (addressing the important gating function performed by *Actavis*'s "unjustified" prong).

For these reasons, the district court's dismissal must be affirmed under Rule 12 and *Actavis*. (Appellants' legal conclusions, draped as allegations, that Forest could not have prevailed in the patent litigation are meritless. *Cf. 1-800-CONTACTS*, 1 F.4th at 120 (2d Cir. 2021).)

EXPLICATED STANDARD OF REVIEW

Review of dismissal under Rule 12(b)(6) requires this Court to assess firsthand whether the allegations adequately state a claim—which necessarily requires testing those allegations against documents plaintiffs incorporate by reference into a complaint. *See Admiral Ins. Co. v. Niagara Transformer Corp.*, 57 F.4th 85, 91 (2d Cir. 2023) ("[W]e draw all facts—which we assume to be true ***unless contradicted by more specific allegations or documentary evidence***—from the complaint and from the exhibits attached thereto[.]") (emphasis added); *Zervos v. Verizon N.Y., Inc.*, 252 F.3d 163, 168 (2d Cir. 2001) ("When we review a district court's decision de novo, we take note of it, and study the reasoning on which it is based. However, our review is independent and plenary; as the Latin term suggests, we look at the matter anew, as though the matter had come to the courts for the first time.").

ARGUMENT

I. THIS COURT REGULARLY AFFIRMS DISMISSALS UNDER RULE 12 WHERE DOCUMENTS BROUGHT UP BY THE COMPLAINT CONTRADICT THE ALLEGATIONS AND THE PLAINTIFF'S HOPED-FOR INFERENCES.

Roman One of Appellants' argument ignores the context here: Appellants challenge written contracts whose provisions this Court must assess under Rule 12. Appellants cite some general case law according plaintiffs certain favorable inferences from factual allegations. Br. 26-28. But those cases are really beside the

point given this Court's long line of more specific precedents holding that documents incorporated by reference into the complaint readily trump contradictory allegations and proposed inferences, *e.g.*:

- *Goe v. Zucker*, 43 F.4th 19, 28-29 (2d Cir. 2022) (affirming dismissal: "Plaintiffs argue that the district court misapplied the Rule 12(b)(6) standards by relying on contested facts contained in exhibits submitted by Defendants in support of their motions to dismiss, as these were documents extrinsic to the FAC. . . . [A] complaint is considered to include a document incorporated in it by reference, or where the complaint relies heavily upon its terms and effect.") (cleaned up);

- *Blue Tree Hotels Inv. (Canada), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 222 (2d Cir. 2004) (affirming 12(b)(6) dismissal: "But such an inference is belied by the letters attached to the Blue Tree Owners' complaint in which the Blue Tree Owners objected to the manner in which Starwood was allocating vendor payments.");

- *Harty v. W. Point Realty, Inc.*, 28 F.4th 435, 442 n.2 (2d Cir. 2022) (affirming 12(b)(1) dismissal: "[W]here a court erroneously disregards factual evidence *contradicting* a complaint, such an error necessarily subjects the defendant to the significant costs of participating in a litigation that should not have been permitted in the first place.");

- *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 146-47 (2d Cir. 2011) (affirming 12(b)(1) dismissal: "It is well established that we need not credit a complaint's conclusory statements without reference to its factual context. Furthermore, where a conclusory allegation in the complaint is contradicted by a document attached to the complaint, ***the document controls and the allegation is not accepted as true***.") (cleaned up) (emphasis added).

None of Appellants' cited cases (Br. 26-28) address a court's obligation to assess complaint documents under Rule 12. As noted, *supra* 1-2, *Anderson News*, for example, did *not* involve an antitrust challenge to *written* contracts that the

Rule 12 court could hold up to the light alongside the plaintiff's allegations. That is not the case here.

For example, concerning the Hetero transaction, Appellants contend that they were deprived favorable inferences because "[t]he district court's inference that Hetero offered a lower price than [existing supplier] Janssen assumes facts that were neither pled nor proven." Br. 45. But Appellants' brief never once mentions the "Meet or Release" provision in the pre-existing Janssen contract that prevented Forest from switching to another supplier unless Janssen first declined to "Meet" a *lower* offer from the would-be supplier (i.e., Hetero). *See* J.A.-0666 §4.3 (vol. 3); S.A.-0090 ("The Janssen supply agreement contained a 'meet or release' provision providing that Forest may buy API from a third supplier, including Hetero, *only* if it is meaningfully cheaper than the supply from Janssen.") (emphasis added).

What's more, Appellants' *complaint* ignores the "Meet or Release" provision in alleging that the Hetero agreement "exceeded the fair value of any products delivered or services rendered by Hetero, and that the agreement was a way for Forest to pay Hetero to induce it not to compete"—the *same* formulaic allegation that Appellants lob *mutatis mutandis* at each of the respective agreements. *See* J.A.-1528-32 ¶¶163-75, J.A.-1533 ¶178, J.A.-1535-36 ¶182, J.A.-1537-38 ¶188, J.A.-1541 ¶196, J.A.-1543, 1549 ¶¶201, 220 (vol. 7).

Forest attempting to sub in Hetero as a *cheaper* alternative to Forest's pre-existing supplier—pursuant to the "Meet or Release" provision that expressly provided *only* for such cheaper substitution—does not support a plausible inference of a "large and unjustified" payment under *Actavis*. Appellants' assignments of error to the district court ring hollow when Appellants shrink from engaging with the key provisions of the challenged agreements that drove the dismissal.

Hetero is but one example. In fact, Appellants fail to cite a single page of *any* of the challenged agreements spanning 540 pages in the Joint Appendix. J.A.-0591–J.A.-1131 (vols. 3-5).

All told, under this Court's precedents cited above, *supra* 23, Appellants are due *no* inferences that ignore or contradict the black-and-white provisions of the challenged agreements.

II. *ACTAVIS* EXPRESSLY REQUIRES A PLAINTIFF TO ALLEGE FACTS PLAUSIBLY SHOWING A "LARGE AND UNJUSTIFIED" REVERSE PAYMENT TO STATE A CLAIM, AN OBLIGATION THAT APPELLANTS EXPRESSLY DISCLAIM.

Roman Two of Appellants' argument attempts to rewrite *Actavis*'s express holding that a plaintiff must adequately plead a "large and unjustified" reverse payment to, *instead*, permit a plaintiff to state a claim by alleging any "large" business transaction contemporaneous with settling a patent case. Nothing in *Actavis*, *Twombly*, or any other case supports such a reformulation.

A. *Actavis*

Appellants begin by attempting to distinguish *Twombly* from *Actavis*: "*Twombly* was a conspiracy case where the plaintiffs alleged only parallel conduct and asked for an inference of an agreement. . . . Unlike mere parallel conduct, reverse payments raise a suspicion of anticompetitive conduct warranting discovery." Br. 29.

But Appellants' attempt to distinguish *Twombly*'s seminal rule for rigorous pleading requirements flounders. *See* 550 U.S. at 558 ("quite another to forget that proceeding to antitrust discovery can be expensive"). After all, *Actavis* does *not* hold, say, or reason that "reverse payments raise a suspicion of anticompetitive conduct warranting discovery." Br. 29.

First, Appellants invoke three phrases from Section II.A in *Actavis* out of context (Br. 29) to support Appellants' contention that an alleged reverse payment is "a *quid pro quo* . . . unlike ambiguous evidence of parallel conduct and does not require additional detail to state a plausible claim." Br. 29. But that section in *Actavis* describes why a "large and unjustified" reverse payment can be anticompetitive and thus is unworthy of the "near-automatic antitrust immunity," 570 U.S. at 158, that had been accorded by some circuits. In other words, it is "large and unjustified" reverse payments that raise the suspicion warranting discovery

(hence the pleading requirement), *not* simply any contemporaneous business transaction.

Not one word of *Actavis* supports Appellants' hoped-for test that *any* business, even fairly valued business, contemporaneous with settling a patent case is problematic and subject to antitrust scrutiny. Indeed, *Actavis* expressly left room for settling parties to enter into business transactions as "traditional settlement considerations, such as avoided litigation costs or fair value for services[.]" *Id.* at 156. Agreements with "large and unjustified" payments are the ones subject to antitrust scrutiny under *Actavis*, not every business agreement that is contemporaneous with settlement.

Had the Court intended a rule that any business contemporaneous with settlement is sufficient to state a claim, it plainly could have said that. (And we know the Court rejected the FTC's proposed presumption of illegality.) Instead, in resolving the Rule 12 question at issue, the Court announced the "large and unjustified" pleading standard for alleged reverse payments. The Court could not have been clearer that it was resolving the *pleading* standard and punting to the lower courts to figure out how to handle subsequent proceedings: "We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.* at 160.

Second, for these same reasons, Appellants' contentions that the district court misapplied *Twombly* and *Actavis* are misguided. Appellants contend:

> The district court asserted that allowing Plaintiffs to proceed without pleading the absence of justification "would do precisely what *Actavis* forbids—place the burden on the defendant to justify *any side deal for goods and services entered into at the same time as an agreement to settle litigation*." SA-0085. The district court got *Actavis* precisely backwards.

Br. 30 (emphasis added).

But the district court's reasoning refers to precisely what it says: "any" business contemporaneous with a patent settlement. The district court made that observation in *rejecting* Appellants' contention that they need *not* plead facts going to *Actavis*'s "unjustified" prong. *See* S.A.-0083 (rejecting "Plaintiffs' argument that it was sufficient that the Prior Complaints alleged large payments"). Thus, the district court correctly observed that defendants have no general burden under *Actavis* to defend *all* contemporaneous business transactions, only those that, first, have been adequately alleged to be "large and unjustified."

Third, to support their any-contemporaneous-business-must-be-enough formulation, Appellants mischaracterize the allegations in *Actavis* itself as merely that "the services had 'little value' and that the 'true point of the payments was to compensate the generics' to delay their launch." Br. 31 (quoting 570 U.S. at 145). Appellants simply ignore that the complaint in *Actavis* pleaded facts sufficient to

allege total payments of at least $243 million, constituting an overpayment of 667%–1,000%. *See supra* 3.

Actavis's "large and unjustified" pleading requirement thus sets the benchmark for "the challenged restraint," Br. 31 (citing *Ohio v. AMEX*), necessary to trigger rule-of-reason burden-shifting in a reverse-payment case. The question that Rule 12 poses to this Court, as it did to the district court, is *not* about resolving any factual disputes, but whether Appellants' formulaic allegations concerning the challenged contracts plausibly allege a "large and unjustified" reverse payment when, for example, by definition the Hetero agreement could only constitute a cheaper alternative for Forest, *see supra* 24-25, or the Alkem agreement expressly ensured Forest a competitive market price, *see infra* 48-49, rather than resembling anything remotely like the gross overpayments alleged in *Actavis*.[7]

[7] Appellants' other cited cases likewise fail to move the needle. *Arista Records* is not a Rule 12 case; it reviewed for abuse of discretion a motion-to-quash ruling. *Pension Benefit* affirmed dismissal of an ERISA case under Rule 12. In the three Rule 12 antitrust cases, the complaints pleaded facts sufficient to state a claim for an anticompetitive restraint—the facts missing here. *See Todd*, 275 F.3d at 212 (pointing to allegations of the specific type and detail of information exchanged between competitors); *Davitashvili*, 2022 WL 958051, at *10, *13-14 (analyzing provisions of challenged written agreements barring restaurants from selling products at a markup); *Keurig*, 383 F. Supp. 3d at 243 (testing plaintiffs' allegations against written "Noncompetition Agreement" incorporated into the complaint and finding the written agreement sufficiently stated a claim for competitors agreeing not to compete).

B. Every Circuit to Apply *Actavis* Under Rule 12 Agrees with the "Large and Unjustified" Pleading Standard.

Like the district court here, the trio of Third Circuit cases that Appellants cite (Br. 32-35) *each* construed *Actavis* to require the plaintiff to allege facts plausibly suggesting a "large and unjustified" reverse payment to state a claim. *See FTC v. AbbVie*, 976 F.3d at 356 ("To survive a motion to dismiss, a plaintiff must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*.") (cleaned up); *Lipitor*, 868 F.3d at 251-52 (same); *King Drug*, 791 F.3d at 393-94 ("*Lamictal*") (same); *see also id.* at 413 n.38 ("[N]othing in this opinion precludes a defendant from prevailing on a motion to dismiss . . . .").

Appellants do not mention that the other two circuits to apply *Actavis* under Rule 12 concur in the pleading requirement. *See Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 715-16 (7th Cir. 2022) (affirming 12(b)(6) dismissal of reverse-payment claim because plaintiffs failed to allege adequately the requisite payment under *Actavis*—despite plaintiffs' contention that "these matters are best characterized as defenses rather than reasons why the complaint is deficient"); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) (requiring "plaintiffs plead information sufficient 'to estimate the value of the term, at least to the extent of determining whether it is "large" and "unjustified"'") (quoting *In re*

Actos End Payor Antitrust Litig., No. 13-9244, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015)).

Each of these cases would dictate the same outcome here. *See, e.g.*, S.A.-0083 (citing *FTC v. AbbVie* for pleading requirement).

In particular, like the gross overpayment alleged in *Actavis*, in *FTC v. AbbVie* the complaint alleged that the brand company entered into a contemporaneous business transaction with the generic company and "expected to lose roughly $100 million in . . . revenues as a result of the deal," 976 F.3d at 357. Appellants have no comparable allegation here. Furthermore, under Rule 12, this Court can discern from the four corners of the challenged agreements here that none compare to the allegations before the Third Circuit (a case the FTC pursued, as opposed to this one).

The other two Third Circuit cases each involved allegations of a competitively significant restraint *not* at issue in any of the settlements here: a so-called "no authorized generic" or "no-AG" agreement. A "no-AG" is an agreement for the brand company to refrain from marketing its own generic version of a product in competition with the generic company's version. The Third Circuit held that the alleged "no-AG" agreements stated a claim for a "large and unjustified" reverse payment because unlike a business transaction for products or services, which have offsetting consideration flowing in both directions, the no-AG agreements

constituted large, one-way transfers of value from the brand company to the generic company. *See Lipitor*, 868 F.3d at 258, 261 (observing "no-AG agreement allegedly constituted a substantial, net payment" that "amounted to over $500 million in value" and entailed "***no exchange of goods or services***") (cleaned up) (emphasis added); *Lamictal*, 791 F.3d at 404, 409 (observing "no-AG agreement would have been worth hundreds of millions of dollars" to the generic company and such an "unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified—whether as compensation for litigation expenses or services, or otherwise—is subject to antitrust scrutiny under the rule of reason").

None of these cases support Appellants' contention that "lower federal courts have consistently recognized that reverse-payment claims are adequately pled without the detail required by the district court here." Br. 32.[8]

[8] Appellants' district court cases also confirm the pleading requirement (Br. 35-36). ***(i)*** The full context of the snippet Appellants quote from *Sergeants Benevolent* reveals that, unlike here, there was a confounding §2 monopolization claim for so-called "product-hopping." 2016 WL 4992690, at *15. ***(ii)*** *Solodyn* confirms that "allegations of a large and unjustified payment are required for plaintiffs to satisfy their initial burden[.]" 2015 WL 5458570, at *7. ***(iii)*** *Aggrenox* observes that "if, when viewed holistically, it effects a large and unexplained ***net transfer of value*** from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement[,]" 94 F. Supp. 3d at 243, then finds that, unlike here, "the complaints make specific allegations about the terms of the settlement ***and their relative value*** that are plausible on their face," *id.* at 245 (emphasis added). ***(iv)*** *Niaspan* describes "large" and "unjustifiable" as "the pleading hurdle posed by *Actavis*," which was met because the alleged "no-AG provision works exactly as would a payment of cash" and plaintiffs alleged additional payments of over

III. APPELLANTS ALL BUT EXPRESSLY CONCEDE THAT THEY DO NOT ALLEGE THE "UNJUSTIFIED" PRONG OF *ACTAVIS*.

Appellants' Roman Three and its nine bullets summarizing Appellants' allegations (Br. 37-38) confirm that Appellants have *not* alleged the "unjustified" valuation component of *Actavis*'s pleading requirement.

Appellants expressly contend that alleging a "large" business transaction contemporaneous with settlement suffices: "Courts on motions to dismiss have focused on the presence of large payments made to induce the generic to settle because *Actavis* puts the burden on the defendant to justify any payment during the litigation. *See supra* pp. 32-37." Br. 40. Appellants simply ignore, however, that each of the cases they cite (Br. 32-37) expressly applies *Actavis*'s conjunctive pleading requirement. *See supra* 30-32.

The "unjustified" component of *Actavis*'s pleading requirement performs an important gating function: without it, there would be no way to discern between anticompetitive reverse payments and those "reflect[ing] traditional settlement

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$100 million. 42 F. Supp. 3d at 745, 750-52. ***(v)*** In *United Food v. Teikoku*, the court said: "[T]o determine if a term is a large and unjustified payment, as *Actavis* requires, courts must be able to calculate its value." 74 F. Supp. 3d at 1069. The court found that pleading requirement satisfied because plaintiffs alleged a "no-AG" agreement and that the brand ***gave*** the generic $96 million of free products, altogether worth $266 million, with no offsetting consideration from the generic. *Id.* at 1068, 1070, 1072. ***(vi)*** Appellants also cite *Cipro* where California's Supreme Court held concerning the Cartwright Act claims at issue: "*Actavis* is not dispositive on matters of state law." 348 P.3d at 858.

considerations, such as . . . fair value for services," 570 U.S. at 156. Despite *Actavis*'s rejection of the FTC's proposed "quick look" test, then, nearly *every* business transaction contemporaneous with settlement would be sufficient to state a claim. *Compare id.* ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the ***challenged term*** and showing the lawfulness of that term under the rule of reason.") (emphasis added), *with* Br. 1 (carefully omitting the words "challenged term" from the same quotation of *Actavis* and replacing them with "[payment]").

As Appellants would have it, the "challenged term" would simply be any "large" business contemporaneous with settlement. Apparently, it is worth it under Appellants' business model as recurring antitrust plaintiffs to test *Actavis*'s limiting principle.

Appellants' remaining Roman-III arguments are no more faithful to *Actavis*. With no supporting authority, Appellants suggest that even if they fail *Actavis*'s pleading requirement as to each settlement, those individually deficient allegations somehow *collectively* state a claim as to all the settlements together. *See* Br. 40. But Appellants cite no authority for such proposition nor do their complaints plead facts supporting any kind of overarching conspiracy among all the defendants—for settlements that Appellants concede occurred separately over a one-year period.

See J.A.-1528-49 ¶¶163-220 (vol. 7); *see also supra* 11-12 (citing FDA guidance on shared first-filer status being commonplace among independently filed ANDAs).[9]

Appellants misleadingly cite *Lynch v. City of New York*, 952 F.3d 67 (2d Cir. 2020), contending "that Forest *was alleged* to have engaged in the same conduct at other times increases the plausibility of Plaintiffs' claims," Br. 41 (emphasis added). Appellants omit that they refer to Forest *settling* a private antitrust suit rather than any type of adjudication. *See Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 894 (2d Cir. 1976) (holding allegations from settled action "immaterial" in a subsequent action). *Lynch* inappositely concerned whether a plaintiff could incorporate sworn deposition testimony into the complaint. 952 F.3d at 82.

Finally, Appellants' contention that, "Plaintiffs' allegations that Forest could not have prevailed in the patent litigation further supports the plausibility of Plaintiffs' claims[,]" Br. 42, is meritless: legal conclusions cannot be credited as factual allegations and Appellants have alleged *no facts* on the purported weakness of Forest's patents. *See supra* 14 & n.4 (citing *Hamilton*, 3 F.4th at 90 (2d Cir. 2021)).

[9] *Continental Ore* (Br. 38) concerned "the duty of the jury" to assess evidence holistically, 370 U.S. at 699; it is not a Rule 12 case and lends no support to Appellants' proposed lowering of pleading requirements for challenges to multiple bi-lateral settlements.

IV. APPELLANTS LARGELY IGNORE THE PROVISIONS IN THE WRITTEN AGREEMENTS THEY CHALLENGE, AND ON THEIR FACE THOSE AGREEMENTS PRECLUDE ANY PLAUSIBLE INFERENCE OF "LARGE AND UNJUSTIFIED" PAYMENTS.

Appellants' Roman Four proceeds from the misguided premise that it is the district court's opinion, rather than the challenged agreements' provisions, that matters in this appeal. Appellants cannot stir up plausibility for their allegations by contending, for example, that the district court did not cite *Anderson News* (Br. 43); this Court regularly affirms Rule 12 dismissals in alleged antitrust conspiracy cases without citing *Anderson News*. *E.g.*, *Alaska Dep't of Revenue v. Manku*, No. 20-1759, 2021 WL 3027170, at *3 (2d Cir. July 19, 2021); *Vedder Software Grp. Ltd. v. Ins. Servs. Off.*, 545 F. App'x 30, 33 (2d Cir. 2013) (summary order); *Mayor & Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 140 (2d Cir. 2013).

Appellants' *modus operandi* is to grasp at peripheral instances where they believe the district court should have accepted some inference in their favor while simultaneously ignoring that the district court squarely held that on the facts alleged the plain language of the at-issue contracts precluded Appellants' proposed inferences of a "large and unjustified" payment. For example:

- *Compare* Br. 44 ("The district court's conclusion that '[t]he more plausible inference is that with a product as specialized as API, there would be no need or opportunity for competitive bidding' (S.A.-0089) is exactly the kind of choice between competing inferences that *Anderson News* prohibits."), *with* S.A.-0090-91 ("The Final Term Sheet thus could not have been a financial windfall to Hetero because Hetero's price necessarily had to be at least 15% lower than Janssen's in order for the Final Term Sheet to take effect."); and

- *Compare* Br. 49 ("[T]he district court rejected Plaintiffs' allegations that there was no public disclosure that Forest was seeking to develop a new form of Bystolic because a 'more plausible inference is that the agreement was simply not material for SEC reporting purposes.' SA-0098. Again, under *Anderson News*, a district court must not assess what inferences are 'more plausible.'"), *with* S.A.-0095-96 ("That Forest had just purchased for $357 million the U.S. patents and intellectual property for Bystolic from Janssen misses the key point evident from the plain language of the agreement: the Patent Assignment Agreement was not for Bystolic, but for the development of a non-Bystolic nebivolol product.").

Rule 12 does not tally inferences; it asks whether a plaintiff's allegations adequately plead facts showing a plausible claim. That is what the district court did in resolving Appellants' allegations based on the challenged agreements, and no amount of cherry-picked language from the district court's opinion can distract from those dispositive agreement terms. In any event, on de novo review, it is for this Court to assess Appellants' allegations alongside the contracts at issue.

The final overarching point concerning each of the agreements is that unlike a peppercorn of consideration under contract law, under *Actavis* the size of the payment matters, *e.g.*, 570 U.S. at 159 ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size"), hence the "large and unjustified" pleading requirement.

Actavis addressed allegations of gross overpayments, *not* allegations about paying $1.10 versus $1. *But see* J.A.-1536 ¶184 (vol. 7) (alleging Alkem received a "10% premium"). And *Actavis*'s holding that an antitrust claim could be had

concerning "large and unjustified" reverse payments came with a backdrop: "Courts are ill suited 'to act as central planners, identifying the proper price, quantity, and other terms of dealing.'" *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 452 (2009) (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)).

None of the nominal compensation terms in this case come *anywhere* near the amounts in *Actavis*, much less the net, ten-fold overpayments alleged there (or the similar staggering sums alleged in the other cases Appellants cite, *see supra* 31-32 & n.8).

Appellants obfuscate the modest financial terms of the agreements here by asserting that "Forest entered into side deals with each Generic Defendant that Forest admitted were worth at least $15 million each." Br. 1. But that makeweight ignores that there were three disjunctive criteria in Forest's 2014 merger disclosure, two of which were unrelated to a $15 million materiality threshold, and one of which expressly applied to "monitoring or reporting obligations" (i.e., Forest's filing of all the agreements here with the FTC and DOJ). *See* J.A.-1136, 1139 §3.20(xiv) (vol. 5); S.A.-0115 ("squarely reject[ing]" Appellants' reliance on a purported $15 million valuation for each agreement because "Plaintiffs focus on only one of the three disjunctive criteria") (cleaned up).

As detailed below, none of Appellants' other allegations plausibly show a "large and unjustified" payment to any of the Generics.

A. Hetero: The Section 4.3 "Meet or Release" Provision in Forest's Pre-Existing Janssen Supply Contract and the Parallel Provision in the Hetero Term Sheet Preclude Appellants' Inferences.

Hetero was the first Generic to settle the patent litigation, and the subsequent Generic settlements achieved the same early-entry date of three months before the '040 Patent expired. J.A.-0609 §1.16 (vol. 3). Appellants concede in their complaints that Hetero and Forest signed their term sheet for the supply of nebivolol API 19 days *before* their patent-litigation settlement, meaning that the only alleged business between Forest and Hetero was a *fait accompli* before settlement. J.A.-1528 ¶163 (vol. 7).[10]

Appellants are wrong that they may simply infer a plausible large and unjustified payment despite the clear terms of the Hetero Final Term Sheet. Appellants first contend that Forest did not need nebivolol API from Hetero because Forest had a "long-standing relationship" with Janssen and a sufficient API supply.

[10] Appellants likewise concede that the Final Term Sheet never resulted in a final supply agreement. J.A.-1530-31 ¶170 (vol. 7). There is nothing anticompetitive inferable from the agreement not consummating. In fact, the Final Term Sheet obligates Forest to first attempt to amend its pre-existing supply agreement with Janssen before Forest could execute *any* business with Hetero. J.A.-0632 ("Obligations," third bullet) (vol. 3). The Final Term Sheet does not provide for any payment if a supply agreement is not consummated.

Br. 43, 46. But Appellants ignore the "Meet or Release" mechanism in Forest's pre-existing contract with Janssen (J.A.-0666 §4.3 (vol. 3)), expressly contemplating Forest's pursuit of alternate supply and providing a mechanism for Forest to seek *cheaper* supply partners. This is undoubtedly a "rational and competitive business strategy[.]" *Twombly*, 550 U.S. at 554.

Next, Appellants contend that the Final Term Sheet was a "rush job" compared to the Janssen agreement and that Appellants are entitled to the "natural inference" that competitive bidding is typical "for supply agreements." Br. 44, 46. But Appellants allege no facts supporting that competitive bidding is typical in the specialized API-supply context or suggesting why Forest would have needed at least *two* cheaper alternatives before trying to lower its cost under the "Meet or Release" mechanism with Janssen; certainly nothing in the Janssen agreement supports that counter-intuitive proposition. *See* J.A.-1528-32 ¶¶163-75 (vol. 7). Indeed, courts have made clear that "[t]he Sherman Act does not require competitive bidding . . . ." *Nat'l Soc'y of Pro. Eng'rs v. United States*, 435 U.S. 679, 694-95 (1978); *see also Brown v. W. Mass. Theatres, Inc.*, 288 F.2d 302, 304 (1st Cir. 1961) ("[A] departure from competitive bidding does not in itself constitute or prove a[n] [antitrust] violation, and cannot be helpful to the plaintiff unless he can rationally relate it to other conduct by the alleged conspirators."). Similarly, Appellants' "rush job" allegation is refuted by §4.3 in the Janssen agreement requiring Forest to provide

Janssen with documentation of a competitive alternate-supply offer *and* Janssen's consent before finalizing the details of any proposed substitution. J.A.-0666 §4.3 (vol. 3).

Ultimately, the real inference sought through Appellants' sufficient-supply, competitive-bidding, and rush-job arguments is that the Final Term Sheet did not reflect fair value and must have included a large and unjustified payment. But the plain terms of the pre-existing Janssen supply agreement and the Hetero term sheet, which Appellants ignore, preclude such inference.

The "Meet or Release" provision in the Janssen agreement expressly preserved and contemplated Forest seeking an alternative supplier solely based on a meaningfully cheaper alternative (i.e., at least 15% cheaper). J.A.-0666 §4.3 (vol. 3). Thus, Forest had a demonstrable interest in finding a lower-cost alternative supplier *well before* any patent settlement with Hetero.

The unequivocal terms of the "Meet or Release" provision in the Janssen agreement also mean that Hetero's offered price of $3,000/kg necessarily was at least 15% *lower* than what Janssen was charging. J.A.-0626, J.A.-0666 §4.3 (vol. 3); J.A.-1528 ¶163 (vol. 7). The parallel "Meet or Release" provision in the *Hetero* agreement serves the same purpose: it ensures that Hetero would also be

bound to meet a competitor's 15%-lower offer or else Hetero would lose its purchase minimums. J.A.-0627-28 (vol. 3).[11]

The pointedly competitive architecture of these agreements thus precludes any inference of the "large and unjustified" windfall alleged in *Actavis* or any "reasonable expectation that discovery will reveal evidence of illegal agreement." *Twombly*, 550 U.S. at 556.[12]

[11] Inclusion of the pricing in the Hetero term sheet follows the Janssen agreement's §4.3 "Meet or Release" provision, which requires Forest to provide the third-party communication—i.e., the Hetero term sheet—documenting the "competitive offer" necessary to trigger the provision. J.A.-0666 §4.3 (vol. 3). This also refutes Appellants' speculation—unsupported by any provision of the agreements—that "[i]f the Janssen agreement granted Forest the right to terminate, Forest would not have needed to amend it." Br. 45. Janssen's consent was necessary because, under §4.3, Forest had to provide Janssen with *documentation* of the "competitive offer," which had to be "for API in the Territory on commercially reasonable terms." J.A.-0666 §4.3 (vol. 3). Forest could not just tell Janssen of Hetero's $3,000/kg offer; Janssen had the contractual (and common-sense) right to review documentation of Hetero's offer to make sure it was comparable on the non-price terms.

[12] Appellants quote *Nexium* as saying that "fair market value is" not "a silver bullet against antitrust scrutiny," Br. 45, but that district judge later confessed his "misconception" of the case and course corrected by instructing the jury that a settlement does *not* raise antitrust concerns where it reflects "traditional settlement considerations and . . . fair value for services." *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107, 139 n.45 (D. Mass. 2015); Trial Tr. at 46-47, *Nexium*, No. 1:12-md-02409 (D. Mass Dec. 11, 2014), ECF 1439 (jury instructions); *see also supra* 30-31 (citing First Circuit's subsequent *Loestrin* decision confirming the "large and unjustified" pleading requirement).

B. Torrent: Appellants' Allegation that Forest Did Not Need Torrent's Patents Because Bystolic Was "Reaching the End of Its Life Cycle" Is Implausible Because 69% of Bystolic's Commercial Lifespan Remained and the Torrent Patent Assignment Agreement Expressly Applied Only to Future Products, Not Bystolic.

Appellants' primary contention is that the Torrent Patent Assignment Agreement "was not justified as necessary to protect Bystolic," Br. 48, because Forest would not purchase new patents for "a product that was reaching the end of its life cycle," having previously spent $357 million to acquire "all" of the patents covering Bystolic, J.A.-1533-34 ¶179 (vol. 7). But the provisions of the Patent Assignment Agreement expressly contradict Appellants' premise.

The Patent Assignment Agreement—which Appellants never cite, let alone discuss in their brief—expressly *excludes* "any nebivolol product that has been produced and marketed by Forest on or before the Effective Date," which means that, under Appellants' own allegations, the agreement excludes Bystolic. J.A.-0942 §1.4 (vol. 4); J.A.-1533 ¶178 (vol. 7) (alleging Bystolic marketed since 2008). Appellants also concede that when the parties executed the agreement, Forest was "developing" a new nebivolol product called Byvalson. J.A.-1534-37 ¶¶181-85 (vol. 7).[13]

[13] Contrary to Appellants' out-of-context suggestion that the district court balanced Appellants' "allegations that there was no public disclosure that Forest was seeking to develop a new form of Bystolic," Br. 49, against a counter-narrative, the district court clearly accorded *no* weight to that allegation because Appellants "*cite no facts*

Shorn of the foundational mis-assumption that the Patent Assignment Agreement purported to, but could not, protect *Bystolic* with the new patents transferred under the agreement, Appellants' remaining allegations collapse, too. Their complaint fails to allege any nexus between the Patent Assignment Agreement's value and either the substantial time then-remaining on Bystolic's commercial life cycle[14] or the much *higher* price ($357 million) that Forest paid a third party for patents that *did* cover Bystolic in an earlier, unrelated transaction. *See* Br. 47-49. And, notwithstanding that the Patent Assignment Agreement is a detailed intellectual-property contract susceptible of objective valuation, Appellants fail to allege *any* valuation of the transferred IP.

Appellants seek to sidestep these deficiencies by suggesting that their conclusory allegation that the Patent Assignment Agreement "had 'little or no value to Forest'" should have been credited "because the $7 million milestone in the Torrent agreement was triggered by issuance of any of the ten assigned patents rather

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for the proposition that Forest . . . would need to disclose [such an intent] in its SEC public filings." S.A.-0097-98 (emphasis added).

[14] Appellants' conclusory allegation that Bystolic was nearing the end of its lifecycle—now omitted from their brief—contradicts Appellants' own allegations. *See* S.A.-0096-97 (observing Forest had *nine years* of exclusive sales between the November 2012 Patent Assignment Agreement and Hetero's September 2021 launch date). Forest only began selling Bystolic in 2008, leaving 69% of its lifespan remaining. J.A.-1531-32 ¶174, J.A.-1533 ¶178 (vol. 7).

than a patent that would have supported a particular reformulation." Br. 48. But the agreement expressly provides that such milestone was payable *only* upon issuance of the specified pending application *in the United States* or any other future application *in the United States* "derived from" any of the foreign-listed patents pursuant to the Patent Co-Operation Treaty. J.A.-0941-42 §1.3, J.A.-0944 §5.1, J.A.-0956 (vol. 4). Contrary to Appellants' atextual allegation, Forest specified a future U.S. patent grant (needed for a U.S. follow-on product like Byvalson) to trigger the milestone payment.[15]

Appellants' remaining contentions are meritless. Appellants contend that "recognizing the plausibility of a reverse payment claim based on a patent assignment agreement does not make every patent assignment agreement presumptively suspect." Br. 46-47 (citing S.A.-0094). But this inverts the district court's reasoning. The district court did not "reason[] that Plaintiffs' allegations were insufficient because" they would have this effect; rather, having concluded that Appellants' allegations failed under *Twombly*, the court observed that merely alleging a so-called "side deal" would presumptively disallow business transactions contemporaneous with settlement, contrary to *Actavis*. S.A.-0094.

[15] As the face of Exhibit A to the agreement shows, the Assigned Patents had been granted in six of the ten listed jurisdictions. J.A.-0956 (vol. 4).

Similarly, Appellants complain that the district court improperly "pointed to evidence in *Provigil* as the kind of evidence that should be pled," Br. 47, because *Provigil* "was a summary judgment opinion." *Id.* But the district court "pointed" to *Provigil* only because *Appellants' complaint expressly relied on Provigil* as the basis for their "overbroad" allegation that all business transactions contemporaneous with settlement necessarily constitute improper reverse payments. S.A.-0094 (citing J.A.-1534 ¶180 (vol. 7)).

C. Alkem: Appellants Allege No Facts Suggesting that Alkem's Per-Tablet Prices of $.02375 and $.0475 Were Abnormal, and Appellants Ignore the Competitive-Pricing Guarantee that Forest Obtained.

With no supporting facts, Appellants assert that Forest did not need Alkem as another manufacturer for the finished-dosage form of Bystolic (i.e., the complete tablet ingested by the patient rather than a manufacturing ingredient like API) because "[n]either publicly available information nor the Term Sheet contain evidence that Forest was experiencing supply shortages . . . for the finished dosage form of Bystolic." Br. 15-16, 50; J.A.-1536 ¶183 (vol. 7). But Forest's 2012 Form 10-K—incorporated by reference into Appellants' complaint, J.A.-1530 ¶168 (vol. 7)—states that Forest had only one qualified manufacturing facility for Bystolic and that "the *inability to locate and qualify third party alternative sources* . . . could lead to shortages or long-term product unavailability, which *could have a material adverse effect on our results of operations, financial condition and cash*

flows," J.A.-1161 (vol. 5) (emphases added). This real-world document, cited in Appellants' complaint, shows Forest's publicly announced need for a second manufacturer.

Again without support, Appellants contend that Forest did not need a manufacturer for Byvalson (the follow-on Bystolic product described in Appellants' complaint) because Forest "had not yet submitted its NDA for Byvalson." Br. 16; J.A.-1535-36 ¶182 (vol. 7). But Forest could not obtain FDA approval without *first* demonstrating to the FDA exactly where and how Byvalson would be manufactured. *See* 21 C.F.R. §314.50(d)(1); 21 U.S.C. §355(b)(1)(A)(iv). Thus, the Term Sheet requires Alkem to first produce "registration batches" as part of the "Development Work" necessary to obtain FDA approval, and then "Commercial Batches" after approval. J.A.-0853-54 (vol. 4).

Next, Appellants assert that the Term Sheet was "one-sided," Br. 16, but they again allege no facts to support that assertion, which the Term Sheet contradicts. First, Appellants allege that the Term Sheet obligated Forest to pay Alkem twice for the same tasks because Forest agreed both to make milestone payments for "Development Work" and to reimburse Alkem for the "costs and expenses incurred in connection with the Development work." Br. 16; J.A.-1536 ¶184 (vol. 7). The Term Sheet says otherwise. The "costs and expenses" were to be paid while the Development Work was underway "in accordance with a mutually agreed work-plan

and budget," J.A.-0856 (vol. 4), but the milestone payments were tied to "*successful completion*" of events like the "Technology Transfer," "Registration Batches," and "release of the Validation Batches," J.A.-0854-55 (vol. 4) (emphasis added). One reimburses indeterminate amounts for Alkem's out-of-pocket outlays, while the other provides fixed value as rewards for distinct developmental accomplishments. Demonstrably, those are not duplicative payments.

Second, Appellants claim that the Term Sheet required Forest to supply Alkem with "free API," but allege no facts to support their speculation that this "likely conferred significant financial benefit." Br. 16; J.A.-1536 ¶184 (vol. 7). Indeed, Appellants say nothing about the value of the API and *ignore* the context of the agreement under which Alkem would process API into finished Bystolic and Byvalson: free API necessarily reduces Alkem's reimbursable expenses.

Third, Appellants allege that Forest agreed to pay Alkem "as much as a 10% premium over 'prices generally available' from other supply sources." Br. 16; J.A.-1536 ¶184 (vol. 7). But Appellants misread this provision. It does not apply to the first five years. The so-called "premium" only applies to renewals in years six and seven of the Agreement, which in turn renews only *if* Alkem "is willing and able to continue to supply Product to Forest at a price which is competitive (i.e., *not more than* 10% higher than prices generally available from such sources)." J.A.-0852

(vol. 4) (emphasis added). The 10% "premium" is therefore actually a market-based cap on how much Alkem can ask Forest to pay.

In fact, Appellants do not even allege that the "*no higher than*" 2.375¢ and 4.75¢ per-tablet pricing set forth in the Term Sheet—which are themselves a ceiling—exceed fair value or are outside the industry norm. J.A.-0855 (vol. 4) (emphasis added). None of this remotely resembles the overpayments alleged in *Actavis*. *See supra* 3.

Fourth, Appellants allege that the Term Sheet required Forest "to make payments even if the Byvalson NDA were delayed." Br. 16; J.A.-1534-36 ¶¶181, 183 (vol. 7). But Forest's obligation only arose if the delay was "due to the *failure of Forest* to perform its obligations or as a result of additional development or regulatory activities required *to be performed by Forest*." J.A.-0855 (vol. 4) (emphasis added). Appellants allege no facts explaining why a term requiring Forest to take responsibility for its own delays would be suspect.

Fifth, Appellants allege that "Forest agreed to purchase 45% of its requirements for both products even though Alkem lacked FDA approval to manufacture finished product." Br. 16; J.A.-1534-35 ¶181, J.A.-1536-37 ¶185 (vol. 7). Appellants again selectively read the Term Sheet. Forest agreed to purchase 45% of its requirements "*[d]uring the supply term of the Agreement*," which was defined as "a term of five years *following Alkem's qualification to supply*

Product." J.A.-0852-53 (vol. 4) (emphasis added). Per the agreement's plain language, then, if Alkem never obtained FDA approval, the "supply term" would never begin, and Forest would have no obligation to purchase.[16]

Finally, Appellants argue the Term Sheet lacks "typical" terms and conditions and characterize it as a "rush job." Br. 16; J.A.-1536-37 ¶185 (vol. 7). But they cite no authority for that conclusory proposition, and Appellants do not specify *any* missing terms or provisions that would otherwise be expected.

D. Glenmark: Appellants Allege No Facts to Support a Plausible Inference that the Payments under the Collaboration and Option Agreement for the Development of an mPGES-1 Inhibitor Drug Were Large and Unjustified.

The collaboration and option agreement with Glenmark for the development of an mPGES-1 inhibitor contains all the hallmarks of a legitimate business agreement and gave Forest the votes to steer the mPGES-1 developmental program. *E.g.*, J.A.-1006-07 §§3.1, 3.2(a) (vol. 5) (establishing Joint Development Committee to oversee R&D, which included at least three Forest representatives on the six-member committee); J.A.-1007-08 §3.3 (requiring quarterly meetings and

[16] Appellants argue the Term Sheet was "one-sided" in favor of Alkem but ignore many other provisions favoring Forest. For example, Alkem is excluded from performing any other manufacturing activities concerning nebivolol during the term of the Agreement and for five years following termination. J.A.-0857-58 (vol. 4). Forest also has the right to inspect Alkem's facilities, "Forest shall own and control all regulatory approvals and applications," and Alkem is required to cooperate. J.A.-0856-57 (vol. 4).

sharing confidential project-development information); J.A.-1008 §3.4 ("monitor[ing] the progress of the mPGES-1 Program," "provid[ing] recommendations [as to] additional development work," "recommend[ing], review[ing] and agree[ing] to modifications to the Development Plan").

Once the project concluded, the mPGES-1 collaboration agreement required Glenmark to provide Forest with the clinical research data and granted Forest the right to make the first offer to commercialize the product. J.A.-1012 §6.4(b)(1), (b)(2) (vol. 5). According to Appellants, that was just a "right to negotiate" and nothing more. Br. 52; J.A.-1539-40 ¶191 (vol. 7). Not so. In addition to granting Forest the first offer, Appellants ignore that the agreement precluded Glenmark from partnering with another company unless that company made a "materially more favorable" offer. J.A.-1013 §6.4(b)(5) (vol. 5). That provision, effectively providing Forest with a right of first refusal, defeats any conclusory allegation that Forest received no value from the deal.

But even more fundamentally, Appellants' reverse-payment claim fails because it is based on little more than the conclusory allegation that the compensation under the collaboration "was not for fair value." J.A.-1540 ¶193 (vol. 7). Appellants plead *no facts* whatsoever to establish any valuation for the various rights that Forest received under the mPGES-1 collaboration. *See id.*

Instead, Appellants argue that pleading facts suggesting unjustified valuation is "not required." Br. 23. That is not the law under *Actavis*. *See supra* 3, 26-27.

Appellants offer three irrelevant reasons why the Court should conclude that Appellants plausibly allege that the mPGES-1 collaboration agreement was a ruse.

First, Appellants allege that Forest did not publicly express interest in mPGES-1 projects before entering the collaboration with Glenmark. Br. 18; J.A.-1538 ¶189 (vol. 7). But the fact that Forest did not publicly announce its interest in an mPGES-1 product says nothing about whether Forest was justified in entering the agreement. According to Forest's 2013 Form 10-K—incorporated by reference into Appellants' complaint, J.A.-1482 ¶20 n.16 (vol. 7)—Forest had an extensive portfolio of "products includ[ing] those developed by [Forest], those developed in conjunction with our partners and those acquired from other pharmaceutical companies and integrated into [Forest's] marketing and distribution systems." J.A.-1163 (vol. 5). Appellants do not allege that it was unusual for Forest, or any other pharmaceutical manufacturer, to pursue development projects without publicly announcing their interest in advance. *See* Br. 51-52. Nor do they explain why it would make business sense for Forest to declare publicly its interest in mPGES-1 before executing a collaboration agreement with Glenmark. *Id.* Doing so only would have increased Glenmark's negotiating leverage to secure a higher deal price.

Second, Appellants suggest that the 2012 mPGES-1 collaboration agreement was structured differently than an earlier 2004 collaboration between Forest and Glenmark. Br. 18; J.A.-1538-39 ¶190 (vol. 7). But there is nothing sinister about two companies entering into different contracts with different terms, eight years apart. *See Iqbal*, 556 U.S. at 679. If anything, the fact that Forest and Glenmark had a pre-existing history of developmental collaboration undermines Appellants' claim rather than supports it. *See* S.A.-0108.

Finally, Appellants point to the mPGES-1 collaboration agreement's allocation of the $15 million payment to a $6 million payment for Forest's option rights and a $9 million contribution for research and development. Br. 18, 52. Appellants argue that the $9 million is "unexplained" solely because that amount was not allocated to the option rights. Br. 52. But the mPGES-1 agreement was not just an option agreement; it was a "*collaboration and* option" agreement. Glenmark undertook the ongoing, open-ended expense of the R&D program, while Forest made its financial contribution, with capped exposure, upfront.

Pharmaceutical investments are always risky. Research and development is expensive, and most development efforts do not result in commercialized products.[17]

[17] Indeed, the cost of developing a new medicine can be over $2.5 billion, and less than 12% of drug candidates that even make it to clinical development ever obtain FDA approval. *See* Meredith E. Foor, *Incentivizing Innovation and Reclaiming*

But pharmaceutical companies take those risks every day (as Forest and Glenmark had done previously together eight years prior to the patent settlement) because discovery of a novel pharmaceutical compound that meets an existing need can result in billions in profits. Appellants fail to offer any factual allegations suggesting that payments under the mPGES-1 collaboration were unexplained, unjustified, or in any other way comparable to the overpayments alleged in *Actavis*, given what Forest stood to gain if the project succeeded.

E. Amerigen: Forest's Contractual Right to Recoup Any Milestones Paid if Amerigen Failed to Commercialize Within Five Years Precludes Any Plausible Inference of a Large and Unjustified Payment.

The provisions in the Binding Term Sheet and Final Collaboration Agreement between Forest and Amerigen show on their face a commercially reasonable transaction for R&D investment and access to Amerigen's drug pipeline. Appellants ignore that the alleged "large" payment to Amerigen was actually a series of milestone investments, paid incrementally and *only after* Amerigen completed stages of development and commercialization for eight U.S. treatments. *See, e.g.*, J.A.-1110-11 (vol. 5). Appellants also ignore that Forest was entitled to select new products of equal value if Amerigen discontinued development of any of the eight

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Balance in the Pharmaceutical Industry: A Case for Secondary Patents, 61 IDEA: L. Rev. Franklin Pierce Ctr. for Intell. Prop. 422, 423-24 (2021).

U.S. products and receive up to 20% of Amerigen's gross margins for those products. J.A.-1113, 1116-17 (vol. 5). And Forest received the right-of-first-refusal for royalty-free sales in Latin America for up to eight products from Amerigen's pipeline. J.A.-1118-19 (vol. 5). Appellants do not allege facts about the value of these various drug products or markets, the industry standards for this type of investment, or the respective parties' need for investment or new revenue streams—i.e., Appellants allege no facts supporting an inference that the agreement represented a large and unjustified payment. In fact, Appellants concede that the manufacturing terms for the Latin American products are "customary and reasonable." J.A.-1541 ¶195 (vol. 7).

Critically, Appellants ignore that the "Termination" provision expressly states that if Amerigen fails to commercialize at least one of the "US products" within five years, then Amerigen must pay back to Forest *all* milestone payments until Forest recoups 100% of the milestone payments. J.A.-1096-97 §5.2, J.A.-1117-18 (vol. 5). And even if Amerigen commercializes one "US product," if there are others that have failed to meet developmental objectives, Forest may still elect to terminate the agreement as to some or all of those products, in which case Amerigen must pay Forest back the milestone payments until Forest has recouped 50% of those payments. *Id.*

It simply does not make sense that a "large and unjustified" payment for alleged generic delay would be structured to enable the payor to recoup the payment *after* the parties have already settled the patent litigation. Forest's recoupment mechanism in the Amerigen transaction is irreconcilable with the overpayments alleged in *Actavis*.

Consequently, of the five challenged business transactions between Forest and the Generics above, Appellants allege the fewest facts concerning the Amerigen transaction. *See* J.A.-1541-42 ¶¶195-99 (vol. 7). Appellants do not attempt to value the terms of the Amerigen transaction or to establish that they are somehow unreasonable. *See* Br. 53-55. Instead, Appellants point to the following allegations as purportedly suggesting a nefarious motive:

- "Publicly available information contained no evidence that Forest had a pre-existing relationship with Amerigen or had ever expressed interest in Amerigen's products";
- "Forest publicly held itself out as a specialty pharmaceutical company focusing on branded drug products, but the majority of the Amerigen products were generic products";
- "Forest did not truly care about what products it was investing in";
- Forest and Amerigen did not execute a "definitive agreement" "until nearly one year" after the Binding Term Sheet, and "just weeks after the FTC issued a Civil Investigative Demand to Forest concerning its Bystolic settlements with the Generic Defendants." Br. 19.

Nothing nefarious can plausibly be inferred from companies simply entering into business transactions contemporaneous with settlement or making such deals

without publicly announcing their intentions beforehand. *See supra* 26-27. Appellants allege no facts suggesting such behavior indicates unlawful intent, and they cite no caselaw suggesting such behavior is suspect under *Actavis*. *See* Br. 53-55.

Finally, Appellants suggest an anticompetitive inference because the parties took 11 months to execute the Final Collaboration Agreement, which occurred after receipt of a CID from the FTC. Br. 55. But this *post-hoc-ergo-propter-hoc* speculation is contradicted by Appellants' own allegations, which simultaneously seek to draw the *opposite* inference when characterizing some of the other agreements as "rush jobs" that somehow *also* suggest improper motives. *See* Br. 13-14, 16.

F. Watson: Appellants Fail to Plausibly Allege How Forest's $7m Loan to Moksha8 in November 2013 Conveyed "Disguised Large Payments of $15 Million or More from Forest to Watson."

Appellants do not plausibly allege that Forest made a payment to Watson *at all*, let alone a large and unjustified reverse payment. *See* S.A.-0113. Thus, Appellants' claim concerning Watson must be dismissed even leaving aside their failure to plead facts under *Actavis*'s "unjustified" prong. *See supra* 17-18.

Appellants' theory relies on a series of transactions involving third-party Moksha8, a Brazilian drug manufacturer that was *not* part of the Bystolic patent litigation and with which Forest and Watson each had an independent, pre-existing

relationship. *See* J.A.-1542-49 ¶¶200-20 (vol. 7). Appellants allege that in November 2013 Forest conveyed value *to Moksha8* by providing it with about $7 million in additional credit, requiring repayment, under a pre-existing loan agreement. J.A.-1546 ¶¶212-13 (vol. 7). This "Letter Agreement" also provided releases to Forest from Moksha8 and other parties. J.A.-1546 ¶213 n.108 (vol. 7). Appellants allege that the value provided to Moksha8 through the Letter Agreement was somehow transferred to Watson, which also entered into a termination and release agreement with Moksha8 (the "Termination Agreement"). J.A.-1546-47 ¶214 (vol. 7). Watson and Moksha8 "agreed to relieve each other" of their respective rights, duties, and obligations under a series of separate agreements they had previously entered to facilitate the marketing of pharmaceutical products in Brazil and Mexico. J.A.-1544 ¶204, J.A.-1546-47 ¶214 (vol. 7). As Appellants' complaint admits, the Termination Agreement required *Watson* to pay $4 million to Moksha8, J.A.-1547 ¶215 (vol. 7). Even if this payment were from Watson to Forest (rather than from Watson to Moksha8, an independent third party), it would still be the opposite of a "reverse payment," which by definition is a payment from the brand company to the generic. Yet Appellants speculate, without alleging any actual facts to support the speculation, that the mutual releases "were worth at least $15 million more" to Watson "than what it paid to Moksha8"—i.e., at least

$19 million—"and that Forest made up the difference to Moksha8." J.A.-1547 ¶215 (vol. 7).

As the district court observed, there is a crucial "defect[]" in Appellants' theory, because they concededly fail to allege "how Forest used the transaction with Moksha8 to transfer this payment to Watson." S.A.-0113. Indeed, the "payment" Forest allegedly routed through Moksha8 was not a payment at all—it was a "loan" of $6.9 million. J.A.-1543 ¶200(b), J.A.-1546 ¶211 n.107 (vol. 7). There is "nothing suspect" about this loan, which "on its face appears to be for fair value." S.A.-0114. But even if Appellants' contrary allegation were indulged, their assertion that the loan was used to conceal a payment to Watson makes no sense. It is implausible to infer that Moksha8, in exchange for *a loan* of less than $7 million from Forest, decided *to give* Watson a payment that "exceeded $15 million," Br. 20.

Unsurprisingly, and as noted above, Appellants allege no facts to support an inference that the mutual Moksha8-Watson releases were worth at least $19 million to Watson. No facts are alleged to "describ[e] the releases" or to provide any "context to estimate their relative value" to Watson. S.A.-0113. The conclusory nature of Appellants' allegations stands in stark contrast to cases in which courts

have allowed reverse-payment allegations premised on alleged underpayments to go forward. *See supra* 31-32 & n.8.[18]

Ultimately, Appellants concede that they have *not* alleged "how value was transferred from Moksha8 to Watson in the three party-transaction." Br. 58; *see also* S.A.-0113 (noting Appellants "outright admit" this gap); J.A.-1547 ¶215 (vol. 7). Appellants nevertheless insist that such a transfer of value can be inferred, but their arguments fall well short of establishing plausibility for at least two reasons.

First, Appellants contend that Forest disclosed the Letter and Termination Agreements as material agreements in its 2014 merger disclosure, which Appellants treat as an admission that the agreements channeled at least $15 million to Watson. *See* Br. 56-57. But as previously detailed, *supra* 38, Appellants mischaracterize the disjunctive disclosure criteria, which are not limited to the value of each agreement. In fact, one of the non-valuation criteria applies to all the agreements here because it included a condition directly relevant to the parties' ongoing FTC/DOJ disclosure

[18] After the initial, without-prejudice dismissal, Appellants amended their complaints to add allegations regarding business activities of Watson, Moksha8, and Forest dating back years before the settlement. J.A.-1543-46 ¶¶203-11 (vol. 7). The district court correctly observed that such allegations are "irrelevant" because they lack any connection to Appellants' claims concerning the November 2013 settlement years later, S.A.-0114, and Appellants notably do not rely upon those allegations on appeal.

obligations.[19] By contrast, the $15 million valuation criterion is facially *inapplicable* because it required disclosure of agreements that involved payments made "*after* the date" of the 2014 Merger Agreement, J.A.-1548 ¶217 (vol. 7) (emphasis added). The Moksha8 and Watson agreements do not fit this criterion because any transfer to Watson in the November 2013 Termination Agreement necessarily would have come *before* the Merger Agreement's February 2014 effective date, not after it. J.A.-1546-47 ¶214 (vol. 7). Appellants' unsupported payment theory is thus *not even* "equally as plausible" to alternative explanations, Br. 57—it directly contradicts the 2014 Merger Agreement language.

Second, Appellants speculate that the Watson settlement *must* have included a hidden reverse payment, purportedly because the first five Generics to settle "entered side deals conferring large payments," and Watson, as the last Generic to settle, "had considerable leverage" to insist on its own payment. Br. 57. Leaving aside Appellants' deficient allegations concerning the other settlements, Appellants cannot subject Watson to the "potentially enormous expense of discovery," *Twombly*, 550 U.S. at 559, based on pure surmise that, if other Generics received a payment from Forest, Watson must have, too. No court has ever suggested that

[19] The fact that the Letter and Termination Agreements "do not identify any monitoring or reporting obligations," J.A.-1548 ¶218 (vol. 7), is irrelevant because these obligations arise under federal law.

merely alleging purported leverage by the settling generic can create a plausible inference of a reverse payment, absent alleged facts identifying an actual value transfer. The Supreme Court did not have to guess how the alleged overpayments in *Actavis* were conveyed and Rule 12 does not permit Appellants to proceed on such conjecture.

CONCLUSION

For the foregoing reasons, Appellants' operative amended complaints fail to state a claim under *Actavis*, and the district court's order of dismissal under Rule 12(b)(6) must be affirmed.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Second Circuit Local Rule 32.1(a)(4)(A). This brief contains 13,860 words (as calculated by the automatic word count function of Microsoft Word), excluding the parts of the brief exempted by Rule 32(f) of the Federal Rules of Appellate Procedure.

This brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure, because this brief has been prepared in 14-point, Times New Roman font, a proportionally spaced typeface, using Microsoft Word 2016.

Dated: July 17, 2023

/s/ Eric Grannon
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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of July, 2023, a true and correct copy of the foregoing Brief for Defendants-Appellees was electronically filed with the Clerk's Office of the U.S. Court of Appeals for the Second Circuit, and further certify that the parties' counsel will be notified of, and receive, this filing through the "Notice of Docket Activity" generated by this electronic filing.

Pursuant to Second Circuit Local Rule 31.1, six copies of the Brief for Defendants-Appellees were also transmitted to the Clerk's Office of the U.S. Court of Appeals for the Second Circuit on this same date.

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