23-410 (L)
In re Bystolic Antitrust Litigation

IN THE

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2023
Argued: December 6, 2023
Decided: May 13, 2024

Nos. 23-410 (L), 23-418 (CON), 23-420 (CON), 23-423 (CON)

Watson Laboratories, Inc.,

Debtor.

CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Hdqtrs. Corp., J M Smith Corporation, on behalf of itself and all others similarly situated, DBA Smith Drug Company, KPH Healthcare Services, Inc., individually and on behalf of all others similarly situated, also known as Kinney Drugs, Inc., Mayor and City Council of Baltimore, UFCW local 1500 Welfare Fund, Teamsters Western Region & Local 177 Health Care Plan, Fraternal Order Of Police Miami Lodge 20, Insurance Trust Fund, Law Enforcement Health Benefits, Inc., Teamsters Local No. 1150 Prescription Drug Benefit Plan, Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees Benefit Fund, Albertsons Companies, Inc., H-E-B L.P., The Kroger Co., Walgreen Co.,

Plaintiffs – Appellants,

v.

Forest Laboratories Inc., Forest Laboratories Ireland, LTD, Forest Laboratories Holdings Ltd., Forest Laboratories, LLC, Allergan Sales LLC, Allergan, Inc., Allergan USA, Inc., Abbvie Inc., Watson Pharma, Inc., Watson Laboratories, Inc.

(NY), Watson Laboratories, Inc. (CT), Watson Pharmaceuticals, Inc., Actavis, Inc., Teva Pharmaceuticals USA, Inc., Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Amerigen Pharmaceuticals Ltd., 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., Glenmark Pharmaceuticals Ltd.,

Defendants – Appellees.*

Before: JACOBS, SACK and NARDINI, *Circuit Judges*.

Forest Laboratories, the brand manufacturer of the high-blood-pressure drug Bystolic, settled patent-infringement litigation that it brought against seven manufacturers of generic versions of Bystolic. Contemporaneously with each settlement, pursuant to which the generic manufacturers agreed to forgo the launch of their products for several years, Forest separately entered into business transactions whereby it paid the generic manufacturers for goods and services. Plaintiffs, who are purchasers of Bystolic and its generic equivalents, sued Forest and the generic manufacturers under state and federal antitrust laws, alleging unlawful "reverse" settlement payments to delay the market entry of generic Bystolic. In Federal Trade Commission v. Actavis, Inc., the Supreme Court held

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* The Clerk of Court is respectfully directed to amend the caption as set forth above.

that reverse payments can "sometimes" violate the antitrust laws if they are large and "unjustified"--but that they do not do so when they represent fair value for goods or services exchanged as part of a *bona fide* commercial relationship. 570 U.S. 136, 141, 153–58 (2013). This is the first time that this Court has considered an Actavis claim.

The United States District Court for the Southern District of New York (Liman, *J.*) twice dismissed the case for failure to state a claim. We agree with the district court that Plaintiffs fail to plausibly allege, as Actavis requires, that any of Forest's reverse payments were unjustified or unexplained, instead of constituting fair value for goods and services obtained as a result of arms-length dealings. We further hold that the district court's application of the pleading law set forth in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), Ashcroft v. Iqbal, 556 U.S. 662 (2009), and this Court's progeny was appropriate, notwithstanding isolated phrases from the district court that have given ground for appeal.

The district court's judgment of dismissal with prejudice is therefore **AFFIRMED**.

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Healthcare Services, Inc. a/k/a Kinney Drugs, Inc.

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John M. Masslon II, Cory L. Andrews, Washington Legal Foundation, Washington, DC, *for Amicus Curiae* Washington Legal Foundation, *in support of Defendants-Appellees.*

DENNIS JACOBS, *Circuit Judge*:

Patents grant innovators of new brand drugs in the pharmaceutical industry a time-limited "right to exclude" competitors, 35 U.S.C. § 154(a)(1), including the manufacturers of cheaper generic versions of those brand drugs--who impatiently wait to market a less expensive clone until the patent expires, or is otherwise dislodged by a successful challenge. At stake in the clash of commercial interests are the financial incentives to develop new drugs and the desire of the public to buy them at a discount as soon as possible. The reciprocal pressures are sharpened by laws of every state that either permit or require pharmacies to substitute generics for their brand analogs (unless the prescribing physician requests otherwise). The ensuing litigations, ordinarily pitting claims of patent infringement against claims of patent invalidity or non-infringement, are often prolonged and expensive--and unless settled impair all the competing interests, including the affordability of the products.

With the Hatch-Waxman Act, see Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress sought to encourage and streamline the approval process for generics while also protecting brand manufacturers' patents and incentives to create new products. Hatch-Waxman disciplines the unruly clash of interests by

choreographing it as follows. Through a special certification, a generic manufacturer can challenge a brand drug's patents and, if it is the first to do so, may obtain a lucrative 180-day period of marketing exclusivity among generics from the first commercial marketing of the generic drug. If such a challenge is brought, the brand manufacturer can respond by filing a patent-infringement lawsuit against the generic manufacturer, which automatically defers approval of the generic drug. Rather than engage in costly, distracting, prolonged and uncertain patent-infringement litigation, the brand manufacturer will often choose to settle, and, in consideration for settlement, generic manufacturers may agree to defer launching their products.

Hatch-Waxman litigation between brand and generic manufacturers plays out against the backdrop of two incongruent legal regimes: patent and antitrust. The patent "monopoly" is, of course, legal--so long as it does not extend "beyond its terms." United States v. Aluminum Co. of Am., 148 F.2d 416, 439 (2d Cir. 1945) (L. Hand, *J.*). But a patent holder's market exclusivity allows for supra-competitive profit, which is at odds with the rule of price competition promoted by the antitrust laws. See United States v. Line Material Co., 333 U.S. 287, 309–10 (1948). Although patents are an exception to this baseline rule, they

are not categorically immune from antitrust scrutiny.

This case involves the "tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act." In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2006), abrogated on other grounds by Fed. Trade Comm'n v. Actavis, 570 U.S. 136 (2013). Forest Laboratories, the brand manufacturer of the high-blood-pressure drug Bystolic, settled Hatch-Waxman patent-infringement litigation with seven manufacturers of generic versions of Bystolic. The settlement agreements were accompanied by contemporaneous transactions in which Forest paid the generic manufacturers for goods and services, such as ingredient supply and product development. As part of the settlement agreements, the generics agreed to forgo marketing their products until several years later--three months before the expiration of Forest's Bystolic patent.

The Plaintiffs-Appellants ("Plaintiffs") are purchasers of Bystolic and its generic versions. They brought state and federal antitrust claims against Forest and the generic manufacturers (the "Generic Defendants," and together with Forest, the "Defendants"), contending that Forest unlawfully paid off the generic

manufacturers to delay the market entry of their products and prolong Forest's ability to reap monopoly profits. Plaintiffs claim that Forest covered up these illegal payments by pretextually compensating the generics for goods and services that Forest did not truly need; and that without such "side deals," generic Bystolic would have entered the market earlier--whether by the Generic Defendants prevailing in the infringement litigation, entering at risk (i.e., with litigation ongoing) or agreeing to a settlement allowing for earlier market entry.

These sorts of payments are known as "reverse payments" because, unlike a typical settlement payment, the patent-holding plaintiff pays the allegedly patent-infringing defendants even though they have no claim for damages. In Actavis, the Supreme Court held that such payments should be evaluated pursuant to antitrust law's rule of reason, under which courts balance anticompetitive effects against procompetitive benefits. 570 U.S. at 159. Reverse payments may look dubious, but they are not automatically unlawful. Far from it: the Court held that these payments may "sometimes" violate the antitrust laws, id. at 141, but only if they are both "large" and "unjustified," id. at 158. It instructed that whether a reverse payment passes antitrust muster "depends upon its size, its scale in relation to the payor's anticipated future

litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification," including fair value for goods and services exchanged as part of a *bona fide* commercial relationship. Id. at 156, 159.

Defendants moved to dismiss Plaintiffs' Actavis claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. The United States District Court for the Southern District of New York (Liman, *J.*) twice dismissed Plaintiffs' claims--first without prejudice, then with prejudice--on the ground that the allegations did not plausibly show an antitrust violation under Actavis. The district court issued two thorough opinions to explain its rulings. In re Bystolic Antitrust Litig. ("Bystolic I"), 583 F. Supp. 3d 455 (S.D.N.Y. 2022); In re Bystolic Antitrust Litig. ("Bystolic II"), 657 F. Supp. 3d 337 (S.D.N.Y. 2023). On appeal, Plaintiffs are supported by the Federal Trade Commission as *amicus curiae*; although, unlike in Actavis, the FTC decided, after investigation, not to bring suit itself against Forest or the generic Bystolic manufacturers. This is the first time that this Court has considered an Actavis claim. Our precedent counsels, however, that "[w]hen the restraint at issue in an antitrust action implicates IP rights, Actavis directs us to consider the policy goals of the relevant IP law."

1-800 Contacts, Inc. v. FTC, 1 F.4th 102, 121–22 (2d Cir. 2021) (per curiam).

We affirm the district court's judgment of dismissal for reasons similar to those articulated in its thorough opinions, even though stray phrases may have suggested grounds for appeal.

While Actavis is not self-reading, we agree with the district court that Plaintiffs fail to plausibly allege--as Actavis requires--that Forest's reverse payments were unjustified or unexplained. We further hold that the district court properly applied the pleading law set forth in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), Ashcroft v. Iqbal, 556 U.S. 662 (2009), and this Court's progeny, notwithstanding isolated phrases that might have suggested otherwise. Plaintiffs do not plausibly allege that Forest's reverse payments were sham and pretextual rather than payments that constituted fair value for goods and services obtained as a result of arms-length dealings. Reverse payments for these "traditional settlement considerations," as Actavis understood them, will not advance an antitrust claim to discovery. 570 U.S. at 156.

I

The Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301–399i, imposes a lengthy, rigorous and expensive application process for drug

manufacturers to obtain FDA approval to sell a new drug. A brand manufacturer must submit a New Drug Application ("NDA") that includes, among other things, "full reports of investigations" into whether the drug is safe and effective; a "full list" of the drug's components; a "full statement" of the drug's composition; and a "full description" of the methods, facilities and controls used to manufacture, process and pack the drug. § 355(b)(1)(A). Once the NDA is approved, the FDA lists patents identified by the applicant in the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." See § 355(b)(1)(A)(viii), (c)(2). A patent-infringement claim "could reasonably be asserted" for these patents in connection with the new drug. § 355(b)(1)(A)(viii).

The Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, simplified and accelerated the approval process for generic substitutes of brand drugs. Approval of the brand manufacturer's NDA allows other manufacturers to seek approval of generic equivalents without many of the hurdles required for brand approval. See § 355(j). "[P]iggy-backing on the brand's NDA," Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–05 (2012), a generic manufacturer submits

an abbreviated new drug application ("ANDA") that relies on the brand drug's scientific findings of effectiveness and safety, and must show, among other things, that the generic drug is equivalent to the brand drug as to the active ingredients, route of administration, dosage form, strength, and otherwise, see § 355(j)(2)(A).

The Hatch-Waxman Act established a detailed regime intended to anticipate and timely resolve patent-infringement litigation between brand and generic manufacturers. A generic manufacturer's ANDA must include a certification that its product does not infringe any of the brand drug's patents (i.e., those listed in the Orange Book). There are four options: (I) the brand manufacturer has not submitted patents with its NDA; (II) the brand's patents have expired; (III) the brand's patents will expire on a certain date; or (IV) the brand's patents are "invalid or will not be infringed" by the generic. § 355(j)(2)(A)(vii). Selecting the last option, known as a Paragraph IV certification, constitutes a notional act of patent infringement, affording a cause of action for the brand manufacturer--which must be given notice of the Paragraph IV certification, § 355(j)(2)(B)--and allowing the generic to challenge a patent without risking infringement damages by actually bringing its product to market,

see 35 U.S.C. § 271(e)(2).

This "highly artificial act of infringement," Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990), sets the brand and generic manufacturers on the path to litigation--and, often, eventual settlement. If the brand manufacturer brings a patent-infringement suit within forty-five days of receiving notice of the Paragraph IV certification, the FDA ordinarily cannot approve the ANDA--i.e., allow the generic drug to be marketed--until the earlier of (a) thirty months after the brand manufacturer receives the Paragraph IV notice or (b) a court's ruling that the brand's patents are invalid or not infringed.[1] See 21 U.S.C. § 355(j)(5)(B)(iii). (A generic manufacturer that markets its drug after thirty months without a finding of invalidity or non-infringement would risk being liable for infringement damages.)

The Hatch-Waxman Act "provides a special incentive" for generic manufacturers to challenge brand-drug patents. Actavis, 570 U.S. at 143. The first generic applicant to file an ANDA with a Paragraph IV certification may

[1] If the brand manufacturer does not file a patent-infringement suit during this forty-five-day window, the FDA can immediately approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

benefit from a 180-day exclusivity period starting from the first commercial marketing of its drug--during which it is the only generic manufacturer that can market its drug. See § 355(j)(5)(B)(iv). This 180-day period potentially nets the first filer hundreds of millions of dollars. Actavis, 570 U.S. at 144. When there are multiple first filers on the same day, they share the 180-day exclusivity period.[2] See § 355(j)(5)(B)(iv). (Of course, first filers often face a patent-infringement suit from the brand manufacturer that automatically stalls approval of the generic drug.)

II

Patent Proceedings and Litigation Settlements. Bystolic is a "beta blocker" designed to treat high blood pressure, JA 1475–76 (Compl. ¶ 1);[3] it is otherwise known as nebivolol hydrochloride, and its active ingredient is

[2] Shared exclusivity periods are common when, as here, ANDAs cannot be filed until a particular date: because Bystolic has an active ingredient that constitutes a "new chemical entity," an ANDA could not be filed for five years after Bystolic's approval in December of 2007 unless, as here, the ANDA included a Paragraph IV certification--in which case it was permitted to be filed after four years. See 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108.

[3] "JA" refers to the Joint Appendix. "Compl." and "Complaint" refer to the Third Consolidated and Amended Class Action Complaint located at JA 1471–1584.

nebivolol. Forest's Bystolic NDA included U.S. Patent No. 6,545,040 (the "'040 Patent") for listing in the Orange Book.[4] The '040 Patent issued on April 8, 2003, and expired on December 17, 2021.

Seven generic manufacturers were first to file ANDAs with Paragraph IV certifications for the '040 Patent: Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson--i.e., the Generic Defendants. The Generic Defendants were therefore all entitled to a 180-day marketing exclusivity period. In February of 2012, the Generic Defendants notified Forest that they had filed Paragraph IV certifications. The next month, Forest timely filed patent-infringement lawsuits in federal district court against all the Generic Defendants based on the '040 Patent. These cases, which were consolidated into In re Nebivolol ('040) Patent Litigation (the "Nebivolol Patent Litigation"), 12-cv-5026 (N.D. Ill.), automatically tabled FDA approval of generic Bystolic, see 21 U.S.C. § 355(j)(5)(B)(iii), (j)(5)(F)(ii).

Between October of 2012 and November of 2013, Forest and the seven Generic Defendants reached separate settlements of the Nebivolol Patent

[4] Although Forest submitted another patent, U.S. Patent No. 5,759,580, it did not assert this patent in litigation against the Generic Defendants.

Litigation. Forest and each Generic Defendant agreed to dismiss all claims, defenses and counterclaims in the litigation, and to broadly release each other from related liability. Forest also agreed to pay the Generic Defendants--in either fixed sums or amounts subject to maximums ranging from $200,000 to $2 million--for both Forest's saved legal expenses and the Generic Defendants' expended legal fees and costs.

The settlements also granted each Generic Defendant a non-exclusive, royalty-free license to market its version of generic Bystolic beginning on September 17, 2021, three months before the expiration of the '040 Patent. If any of the Generic Defendants entered the market earlier, all of them would be permitted to launch at the same time as the first market entrant. The effect of these "contingent-launch provisions"--also known as "acceleration clauses"--was to "increase competition in the event that other generics entered the market earlier than contemplated by the agreement[s]." In re Actos End Payor Antitrust Litig., No. 13-cv-9244, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015) (Abrams, *J.*) (holding that similar acceleration clauses were not plausibly anticompetitive under Actavis), vacated in part on other grounds, 848 F.3d 89 (2d Cir. 2017).

Contemporaneously with the settlement and licensing agreements, Forest

entered into other transactions with the Generic Defendants in which it agreed to pay them for various goods and services, such as supplying drug ingredients or developing new products (the "Commercial Transactions"). See infra Part VI (describing transactions in detail). Plaintiffs contend that the payments Forest made to the Generic Defendants pursuant to the Commercial Transactions were unlawful under Actavis, citing, among other things, Forest's counsel's characterization of the transactions in emails as "side deals" and "side agreements" for the Nebivolol Patent Litigation. JA 1524–25 (Compl. ¶ 152). Plaintiffs also emphasize the purportedly large size of the payments by citing a merger agreement between Forest and another company, which lists the transactions as "material," JA 1525 (Compl. ¶ 153); and one of the ways a settlement contract is considered material is if it involves payments of more than $15 million. But a contract was likewise defined as material if it imposed monitoring or reporting obligations; and it happens that federal law obligated Defendants to file the Commercial Transactions with the FTC and the Antitrust Division of the Department of Justice, see Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1112, Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2461–62 (21 U.S.C. § 355 note).

For reasons explained below, we agree with the district court that Plaintiffs fail to plausibly allege that the transactions at issue are outside the parameters allowed in Actavis. We consider them one by one in Part VI.

Procedural History. Plaintiffs are a proposed class of wholesalers of Bystolic and its generic equivalents ("Direct-Purchaser Plaintiffs"); retail-company purchasers of brand and generic Bystolic ("Retail-Purchaser Plaintiffs"); and a proposed class of end payors of brand and generic Bystolic, including health and welfare benefits plans ("End-Payor Plaintiffs"). Defendants are Forest, the seven Generic Defendants (Alkem, Amerigen, Glenmark, Hetero, Indchemie, Torrent and Watson), and related business entities. The Direct-Purchaser Plaintiffs and Retail-Purchaser Plaintiffs brought suit under Sections 1 and 2 of the Sherman Act; the End-Payor Plaintiffs sued under state antitrust and consumer-protection law, as well as Section 16 of the Clayton Act for injunctive and declaratory relief based on violations of Sherman Act Sections 1 and 2.

Section 1 of the Sherman Act forbids any "contract, combination . . . or conspiracy, in restraint of trade or commerce," 15 U.S.C. § 1, by which Congress intended to prohibit "only unreasonable restraints," State Oil Co. v. Kahn, 522

U.S. 3, 10 (1997). Section 2 makes it unlawful to "monopolize, or attempt to monopolize, or combine or conspire . . . to monopolize any part of the trade or commerce." 15 U.S.C. § 2. Illegal monopoly power in a particular market, which is willfully acquired or maintained, is distinct from the legally permissible power that results from "growth or development as a consequence of a superior product, business acumen, or historic accident." United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

The Direct-Purchaser Plaintiffs' and End-Payor Plaintiffs' actions were consolidated and coordinated under one docket along with the Retail-Purchaser Plaintiffs' actions. Defendants moved to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), and the district court initially granted the motions without prejudice. Bystolic I, 583 F. Supp. 3d at 498. After amended complaints were filed, Defendants renewed their motions to dismiss. The district court ruled that the new allegations did not cure the pleading deficiencies, and dismissed with prejudice. Bystolic II, 657 F. Supp. 3d at 371. The district court held--as it did previously--that "[p]laintiffs' factual allegations regarding the side deals . . . do not show that they are large *and* unjustified." Id. at 352 (emphasis added).

Plaintiffs' actions come to us on appeal as consolidated cases. Plaintiffs concede that the complaints are largely similar, and the parties therefore refer primarily to the Direct-Purchaser Plaintiffs' Third Consolidated and Amended Class Action Complaint. We do so as well.

III

We review *de novo* the district court's dismissal of Plaintiffs' complaints under Rule 12(b)(6) for failure to state a claim. City of Pontiac Police & Fire Ret. Sys. v. BNP Paribas Secs. Corp., 92 F.4th 381, 390 (2d Cir. 2024). We accept all well-pleaded allegations as true and interpret them favorably to the Plaintiffs.[5] Id.

To withstand a motion to dismiss, the facts alleged must be sufficient to "state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678. A facially plausible claim is one that "allows the court to draw the reasonable

[5] We need not "credit a complaint's conclusory statements without reference to its factual context." Iqbal, 556 U.S. at 686–87. Crucial context for this case is provided by the actual agreements between Forest and the Generic Defendants, which we can consider even at the pleading stage. See Broder v. Cablevision Sys. Corp., 418 F.3d 187, 196 (2d Cir. 2005) ("Where a plaintiff has relied on the terms and effect of a document in drafting the complaint, and that document is thus integral to the complaint, we may consider its contents even if it is not formally incorporated by reference." (cleaned up)).

inference that the defendant is liable for the misconduct alleged." Id.

At minimum, the allegations must "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. When the court can infer only a "mere possibility" of liability, "the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" Iqbal, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)). The same goes for allegations that are "merely consistent with" but do not plausibly suggest liability. Twombly, 550 U.S. at 557. Mere "labels and conclusions" are insufficient, id. at 555; and absent "further factual enhancement," "naked assertion[s]" will not salvage a complaint otherwise subject to dismissal, Iqbal, 556 U.S. at 678.

Twombly's plausibility requirement is an important safeguard in cases, such as this, that present the prospect of "propelling defendants into expensive antitrust discovery." Mayor & City Council of Baltimore v. Citigroup, Inc., 709 F.3d 129, 137 (2d Cir. 2013). There is no "heightened pleading standard" in antitrust cases, City of Pontiac, 92 F.4th at 390–91, but "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue," Verizon Commc'ns. Inc. v. L. Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004). At the same time, courts "may not properly dismiss a complaint that

states a plausible version of the events merely because the court finds a different version more plausible," since "[t]he choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion." Anderson News, L.L.C. v. Am. Media, Inc., 680 F.3d 162, 185 (2d Cir. 2012); see id. at 184 ("Because plausibility is a standard lower than probability, a given set of actions may well be subject to diverging interpretations, each of which is plausible.").

Given that there are several allegedly unlawful agreements at issue, we avoid "tightly compartmentalizing the various factual components [of Plaintiffs' case] and wiping the slate clean after scrutiny of each." Cont'l Ore. Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962). This means scrutiny of each of the Commercial Transactions on its own merits--but with an eye toward the overall settlement of the Nebivolol Patent Litigation.

IV

In Federal Trade Commission v. Actavis, 570 U.S. 136 (2013), the Supreme Court made clear that reverse-payment settlements are not per se or presumptively illegal--rather, they may violate the antitrust laws only "sometimes." The Court recognized and undertook to navigate the "tension

between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 659 (2d Cir. 2015).

Generic manufacturers--one of which was Actavis--had filed ANDAs with Paragraph IV certifications for generic versions of AndroGel--a brand-name drug produced by Solvay. Actavis, 570 U.S. at 144–45. Solvay filed patent-infringement suits against the generic manufacturers, and the parties settled. Id. at 145. The generic manufacturers agreed to defer the launch of their products until an agreed-upon date earlier than the expiry of Solvay's patent--and to perform services for Solvay, including promoting AndroGel. Id. In exchange, Solvay agreed to pay the generic manufacturers millions of dollars; according to Solvay and the generic manufacturers, this was compensation for the services. Id.

After conducting an investigation, the FTC sued, contending that the promised services "had little value," and that "the true point" of Solvay's payments to the generic manufacturers was to compensate them "for agreeing not to compete against AndroGel." Id. The district court dismissed the FTC's

complaint, and the Eleventh Circuit affirmed, relying on the rule that "a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012). The Supreme Court reversed, rejecting the Eleventh Circuit's scope-of-the-patent test and explaining that looking solely at "what the holder of a valid patent could do" is not dispositive for antitrust purposes, because although a valid patent confers a right to exclude infringing products and charge supra-competitive prices, the same is not true for an invalidated (or not-infringed) patent. See Actavis, 570 U.S. at 147. Hatch-Waxman infringement litigation places "the patent's validity at issue, as well as its actual preclusive scope," and reverse-payment settlements preclude a court from ruling on those questions. Id.

The Actavis Court concluded that reverse payments must be evaluated pursuant to patent and antitrust law both. See id. at 148 ("[P]atent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."). The Court then identified several considerations that bear upon analysis of reverse payments, two of which call for emphasis.

First, reverse payments have the "potential for genuine adverse effects on competition." Id. at 153. That is because (the Court explained) a reverse payment may be effectively a "purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." Id. at 153–54. The Court conceded that settlements allowing earlier launch of generics--as here--would "bring about competition" and benefit consumers, but that reverse payments made solely in order to delay generic market entry "simply keep[] prices at patentee-set levels" and divide monopoly profits between the patent holder and challenger. Id. at 154. A reverse payment, therefore, may evidence the brand manufacturer's desire to "induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." Id.

Second, the anticompetitive consequences of a reverse payment "will at least sometimes prove unjustified." Id. at 156. Critically, the Court recognized that there may be "offsetting or redeeming virtues": the reverse payment may constitute an estimate of saved litigation expenses, or "reflect compensation"--i.e., "fair value"--"for other services that the generic has promised to perform--such as

distributing the patented item or helping to develop a market for that item." Id. ("There may be other justifications."). When a reverse payment is made for such "traditional settlement considerations," the Court explained, "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," and "the parties may have provided for a reverse payment without having sought or brought about" anticompetitive effects. Id. In Actavis, however, this possibility did not "justify dismissing the FTC's complaint" then before the Court. 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."). The Court summarized its reasoning:

> [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 to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.

Id. at 158.

Having reached these conclusions, the Actavis Court rejected the FTC's proposal to deem reverse payments presumptively unlawful and subject them to a "quick look" approach rather than a standard analysis under antitrust law's rule of reason. Id. at 158–59. The rule of reason, which ultimately requires plaintiffs to show that an agreement is "in fact unreasonable and anticompetitive," Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006), ordinarily entails three steps: (1) the plaintiff has the initial burden to show that the challenged restraint of trade has actual anticompetitive effects; (2) if the plaintiff makes out a prima facie case, the burden shifts to the defendant to demonstrate the restraint's procompetitive benefits or justifications; and (3) if the defendant does so, the burden shifts back to the plaintiff to establish that there were less restrictive means for obtaining the procompetitive benefits, 1-800 Contacts, 1 F.4th at 114.

By contrast, the quick-look approach automatically and rigidly places the burden to show evidence of procompetitive benefits on defendants. Actavis, 570 U.S. at 159. The Court concluded that reverse payments do not fall into the limited category of restraints for which "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." Id. That is

so, the Court explained, because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[6] Id.

While Actavis is not self-reading, several general principles can be helpfully distilled from it:

- Reverse payments are subject to a familiar rule-of-reason analysis, rather than the quick-look approach urged by the FTC. Id. at 158–59. Reverse payments, therefore, are subject to antitrust scrutiny because they carry the "*potential for* genuine adverse effects on competition"--but they are not presumptively unlawful. Id. at 153 (emphasis added).

- Reverse payments violate the antitrust laws only "sometimes." Id. at 141. The "relevant antitrust question" is *why* the reverse payment was made. Id. at 158. A reverse payment is unlawful only if made to bring about anticompetitive harm--i.e., to induce the generic manufacturer to stay out of the market, and to maintain monopoly profits to share between the brand and generic manufacturer. See Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 714 (7th Cir. 2022) (Easterbrook, *J.*) ("Actavis adds that *one kind* of settlement, in which the patent holder pays the

[6] Chief Justice Roberts dissented, joined by Justices Scalia and Thomas. Agreeing with the Eleventh Circuit's scope-of-the-patent test, the dissent argued that, because a patent "carves out an exception to the applicability of antitrust laws," courts should "ask whether the settlement gives [the brand manufacturer] monopoly power beyond what the patent already gave it." Id. at 160 (Roberts, *C.J.*, dissenting).

potential entrant to defer entry, could be unlawful when the payment exceeds any reasonable estimate of the costs of litigation and is best understood as a portion of the spoils from a market-division agreement." (emphasis added)).

- We analyze reverse payments against the backdrop of a strong policy "favoring the settlement of disputes," Actavis, 570 U.S. at 153, which applies with full force to patent litigation, see, e.g., Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed Cir. 2001) ("[T]here is a strong public interest in settlement of patent litigation[,] and . . . upholding the terms of a settlement encourages patent owners to agree to settlements—thus fostering judicial economy."); see also Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, *J.*, sitting by designation) ("[*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."). An overly restrictive interpretation of Actavis "would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." Asahi, 289 F. Supp. 2d at 994.

- A reverse payment can violate the antitrust laws only if it is both (1) "large" and (2) "unjustified," or unexplainable. Actavis, 570 U.S. at 158. Both of these prongs must be plausibly alleged at the pleading stage pursuant to the general pleading principles set forth in Twombly and Iqbal.

- As to whether a reverse payment is sufficiently "large," courts should focus on the payment's absolute size and "scale in relation to the payor's anticipated future litigation costs." Actavis, 570 U.S. at 159; see also id. at 158 ("[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.").

- Most important for this case, whether a reverse payment is "unjustified"

> turns on whether it "reflects traditional settlement considerations," including "fair value" for products or services provided by the generic manufacturer pursuant to a legitimate commercial relationship entered into at arms' length with the brand manufacturer. See id. at 156. A plaintiff must plausibly allege that the payment is a pretext for nefarious anticompetitive motives rather than made pursuant to traditional settlement considerations. Id. at 159; see also id. at 158 ("Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.").[7]

V

Plaintiffs allege that Defendants engaged in a broad anticompetitive scheme whereby Forest, pursuant to separate "side deals" with its counterparties, made unlawful reverse payments in order to keep generic Bystolic out of the market. According to Plaintiffs, Forest used the six Commercial Transactions to pretextually pay the Generic Defendants for products or services it did not truly need. These overpayments, Plaintiffs claim, shielded brand Bystolic from competing with its generic equivalents and enabled Forest to share monopoly

[7] The district court relied on a series of considerations, drawn from the FTC's brief in Actavis--but not mentioned in the Actavis opinion itself--that it thought bore upon whether a reverse payment may be unlawful. We decline to adopt those factors here. Again, the basic question is *why* the payment was made, i.e., was there a "convincing justification" for it apart from a bare desire to prevent generic competition? Id. at 159.

profits with the Generic Defendants. Plaintiffs posit that, were it not for Forest's unlawful reverse payments, generic Bystolic would have entered the market sooner--either by the generic manufacturers settling on terms allowing for market entry even earlier, by prevailing in the infringement litigation against Forest, or by launching their products at their own risk (i.e., with patent litigation pending). And with generic Bystolic available, Plaintiffs contend, consumers would not have had to pay the supra-competitive prices that Forest set for brand Bystolic. Plaintiffs argue that this scheme violated the antitrust laws as the Supreme Court construed them in Actavis.

Supporting Plaintiffs as *amicus curiae*, the FTC contends that the district court's decision conflicts with Actavis, other antitrust authorities and general pleading law. According to the FTC, Plaintiffs pleaded an Actavis claim by alleging "peculiar circumstances" showing that the Commercial Transactions are not explainable as ordinary, arms-length business arrangements unrelated to the Generic Defendants' agreements to not enter the Bystolic market until near the expiration of Forest's '040 Patent.

Viewing the allegations as a whole, we agree with the district court that Plaintiffs fail to plausibly allege that Forest made an "unjustified" reverse

payment under Actavis to any of the Generic Defendants.[8] We further hold that the district court properly applied the general pleading principles established in Twombly, Iqbal and this Court's progeny, notwithstanding isolated phrases from the district court that indicate a weighing of competing plausibilities, and that may have given ground for appeal.[9]

There is no allegation plausibly showing that any of the six Commercial Transactions reflected anything other than "fair value" for goods and services obtained as a result of good-faith business dealings--one of the "traditional settlement considerations" squarely privileged under Actavis. 570 U.S. at 156; see also Citigroup, 709 F.3d at 138 (claim of Sherman Act violation not plausible when defendants' alleged conduct "made perfect business sense"). Plaintiffs mostly rely on speculation and supposition in contending otherwise. Neither

[8] We do not consider whether Plaintiffs satisfy their other burden under Actavis to plausibly allege that the payments were sufficiently "large."

[9] For example, the district court drew inferences that it described as "more plausible" than those Plaintiffs sought to be drawn in their favor. Bystolic II, 657 F. Supp. 3d at 355, 360, 367. While it would be error to choose between plausible inferences, see Anderson News, 680 F.3d at 184–85, and district courts should avoid using language suggesting as much, it is clear in context here that the district court was actually concluding that Plaintiffs' allegations were not plausible, period, see, e.g., Bystolic II, 657 F. Supp. 3d at 355 (describing Plaintiffs' assertion as "nonsensical").

the terms of the Commercial Transactions, nor Plaintiffs' specific allegations concerning those agreements, nor their atmospheric allegations regarding Forest's settlement of the Nebivolol Patent Litigation[10] (whether considered alone or together) constitute a plausible basis to infer that Forest paid its counterparties to avoid generic competition, i.e., "purely so [they] will give up the patent fight" and stay out of the market. Actavis, 570 U.S. at 152. That--and only that--is the anticompetitive evil that Actavis condemns.

"Actavis does not stand for the proposition that parties must reach the most procompetitive settlements possible." King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 408–09 (3d Cir. 2015); see Trinko, 540 U.S. at 415–16 (Sherman Act "does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition"). Nor does Actavis "compel antitrust scrutiny of a

[10] For example, Plaintiffs contend that Forest's supposed lack of genuine interest in dealing with the Generic Defendants is reflected in the timing of the Commercial Transactions--which were entered into around when the Nebivolol Patent Litigation was settled, and when the Generic Defendants agreed to defer the launch of their products. JA 1527 (Compl. ¶ 158); see also, e.g., JA 1526–28 (Compl. ¶¶ 157 (brand and generic firms allegedly contract for goods and services only rarely outside of settlement), 161 (Forest's alleged history of entering into "side deals" to cloak unlawful reverse payments)).

settlement regardless of whether its terms could reasonably be interpreted as a large and unjustified reverse payment." Actos, 2015 WL 5610752, at *14; see id. at *19–20 (holding that plaintiffs did not plausibly allege unlawful reverse payments under Actavis when "crediting Plaintiffs' unsupported assertions that the settlements were unlawful 'payments' would suggest that any and all settlements between a brand and a manufacturer are potentially unlawful"). Of course, as the district court explained, Actavis does not require Plaintiffs to "preempt every possible explanation for the reverse payment." Bystolic II, 657 F. Supp. 3d at 351. Nevertheless, the burden imposed on Plaintiffs by Actavis is to affirmatively "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large *and* unjustified reverse payment." In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 552 (1st Cir. 2016) (emphasis added). Plaintiffs have not done so.

VI

Although the six Commercial Transactions are discussed one by one below, the following reasons for dismissal are overarching:

- The terms of the Commercial Transactions reflect *bona fide* business considerations.

- The size of payments is not sufficiently contextualized or compared to enable us to infer that the payments are plausibly unjustified.

- Forest's need for alternative supplies of active pharmaceutical ingredients ("API") or finished pharmaceutical products was consistent with what Forest previously disclosed to investors.

- A lack of public disclosures about business plans or investments does not necessarily bear upon whether those ventures are truly legitimate or genuine.

- It is sensible for counterparties to enter into condensed term sheets with the expectation of subsequently negotiating definitive agreements that are more detailed.

- Payments for developmental or commercial milestones, or research-and-development expenses, bespeak rational commercial incentives.

- Provisions in the Commercial Transactions that are designed to ensure price competition do not fit with Forest's alleged intention to funnel secret overpayments to the Generic Defendants.

- Agreements between Forest and other counterparties need not be identical to Forest's agreements with the Generic Defendants, or even closely resemble them.

- The agreements' provisions trump allegations of unsupported speculation about nefarious motives.

Hetero. Forest and Hetero entered into a term sheet agreeing to "negotiate and enter into" an API supply agreement that would include specified terms as well as "other terms and conditions that are typical for manufacturing and supply

agreements of active pharmaceutical ingredients."[11] JA 632. Hetero would supply Forest with at least 50% of its annual requirements of Bystolic's active ingredient, nebivolol API, for five years (with possible renewals)--which Forest would then sell and distribute in the U.S. and Canada. Forest was allegedly required to pay Hetero at least $37.5 million in exchange.

Plaintiffs' primary contention is that Forest did not need a nebivolol API supply agreement with Hetero because it already had sufficient supply. They point out that, seven months earlier, Forest entered into a nebivolol supply agreement with Janssen Pharmaceutical NV, pursuant to which Janssen would supply all of Forest's API requirements for the U.S. and Canada through 2021.

The existence of a nebivolol API supply agreement with Janssen, however, does not make it plausible that Forest used its separate agreement with Hetero as a pretext for an unlawful reverse payment. It is not enough to say that "[t]here is no evidence" that Forest needed an alternative API supplier. JA 1530 (Compl. ¶ 168). True, Forest's 10-K filing with the SEC for the fiscal year ending in March 2012 stated that Forest had not "experienced any significant shortages in supplies of active pharmaceutical ingredients." JA 1156. But that statement did not

[11] There is no final API supply agreement in the record.

address its *future* nebivolol API supply needs. Moreover, separate statements in the 10-K expressly identified the "risk factor" that many of Forest's APIs were "only available from a single manufacturing source," and warned that "[d]ifficulties or delays in the product supply chain" or the inability to timely "locate and qualify third party alternative sources" could cause "shortages or long-term product unavailability." JA 1161. It is therefore not plausible that Forest's securing of an alternative nebivolol API supplier for a billion-dollar blockbuster drug was nefarious, especially in light of an "obvious alternative explanation." Twombly, 550 U.S. at 567.

Consistent with Forest's legitimate commercial interests, the Janssen agreement and Hetero term sheet complemented and accommodated each other with provisions in both agreements that together authorized and encouraged Forest to seek out alternative nebivolol API suppliers at lower prices. For example, the Forest-Hetero term sheet included a "meet-or-release" provision providing that if Hetero did not match a third-party offer to supply nebivolol API at a 15%-lower price, Forest's minimum purchase amount would drop from 50% to 20% per year. There was a similar meet-or-release provision in the Janssen agreement. See Gen. Elec. Corp. v. BASF Corp., No. 06-cv-283, 2008 WL 4185870,

at *2 (S.D.N.Y. Sept. 4, 2008) (Buchwald, *J.*) (defining meet-or-release provision as a "way of ensuring *competitive pricing* in a fluid market by assuring purchasers that a supplier will meet its competitors' rates" (emphasis added)). The antitrust laws exist to promote this kind of *price-lowering* commercial arrangement. See Line Material, 333 U.S. at 309–10 ("competition on prices" is the Sherman Act's "rule of congressional purpose").

Plaintiffs' remaining allegations do not save their claim. First, they argue it is suspicious that Hetero, unlike Janssen, had no experience with Bystolic and no history of doing business with Forest in this area. That argument fails to recognize that Hetero was planning to market a generic version of Bystolic that contained the same active ingredient. And Hetero's likely ability to fill the supplier role made it a logical business partner regardless of whether the two companies had previous dealings of some kind. Second, Plaintiffs call the term sheet a "rush job" because it was brief compared with the Janssen agreement, and lacked typical terms and conditions. JA 1530–31 (Compl. ¶ 170). The term sheet, however, was explicitly a preliminary set of terms to precede a more comprehensive document "to be entered into." JA 626. Third, Plaintiffs assert that there is no public information suggesting that Forest conducted a

bid-selection process for its nebivolol API supply. The Complaint offers nothing to demonstrate that competitive bidding was typical (or practical) with a specialized chemical compound; and there is no allegation that such a process did not take place, or that (if it did) Forest would be required to publicly disclose it. In any event, "[t]he Sherman Act does not require competitive bidding"--it only "prohibits unreasonable restraints on competition." Nat'l Soc'y of Pro. Eng'rs v. United States, 435 U.S. 679, 694–95 (1978).

Torrent. Forest and Torrent executed a patent-assignment agreement that expressly excluded Bystolic, whereby Torrent agreed to assign (i.e., sell) Forest ten patents for the composition or manufacture of a new nebivolol drug product to be marketed and sold in the U.S. Around that time, Forest was developing another nebivolol drug called Byvalson (composed of nebivolol and valsartan).

In exchange, Forest agreed to pay Torrent $5 million upfront and to make milestone payments of up to an additional $12 million. Of the milestone payments, $7 million was owed to Torrent following the issuance of one of the ten assigned patents in the U.S.; only one such payment was owed irrespective of how many of the ten patents issued there. Forest agreed to assist Torrent in prosecuting the patents, to increase the chances of issuance. The remaining $5

million in milestone payments was triggered upon the earliest of five events:

- Forest submitting a NDA for a new nebivolol drug covered by one of the assigned patents;
- Forest selling such a drug in the U.S.;
- Forest suing a third party for infringement of an assigned patent in the U.S.;
- Forest licensing an assigned patent to a third party; and
- Forest and Torrent having a reasonable basis to believe that a third party is infringing an assigned patent.

Plaintiffs posit that several features of the patent-assignment agreement are anticompetitive. They claim, implausibly, that the milestones triggering the additional $12 million total in payments were easy to achieve. As to the $7 million milestone payment, although a pending application for one of the assigned patents was eventually granted, this did not occur until January of 2014--more than a year after Forest and Torrent entered into the patent-assignment agreement.[12] With respect to the additional $5 million

[12] It is further alleged that the assigned patents "had little or no value," JA 1534 (Compl. ¶ 179), given that the $7 million payment was triggered by the issuance of any patent--rather than a particular patent--in the U.S. But the patent-assignment agreement supports the opposite conclusion. In November of 2012, when Forest and Torrent entered into the agreement, none of the assigned patents had issued in the U.S., and the application for only one was

payment, the triggering conditions were not plausibly illusory: one was Forest submitting an NDA for a new nebivolol drug; as we have explained, the NDA process is extensive and rigorous, see supra Part I.

Contrary to the allegations, the milestones were "in line with a wide swath of rational and competitive business strategy," Twombly, 550 U.S. at 554: Forest agreed to pay Torrent $7 million upon the issuance in the U.S. of a potentially valuable patent--and $5 million upon the achievement of important milestones that bespeak the desirability and value of that patent and the others. See Pac. Bell Tel. Co., 555 U.S. at 452 ("[C]ourts are ill suited to act as central planners, identifying the proper price, quantity and other terms of dealing." (internal quotation marks omitted)).

Many of Plaintiffs' remaining allegations ignore the evident primary purpose of the patent-assignment agreement: to help Forest develop and market a new nebivolol product. The allegations are flawed in other respects as well.

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pending there. The new nebivolol drug contemplated by the agreement, moreover, was to be "sold and marketed in the United States." JA 942. It stands to reason that the U.S. issuance of any of the assigned patents was valuable to Forest. The triggers for the additional $5 million milestone payment reinforce this conclusion: one was Forest's sale of a new nebivolol drug covered by one of the assigned patents *in the U.S.*, and another was Forest suing for infringement of an assigned patent *in the U.S.*

For example, Plaintiffs deem it implausible that Forest would try to obtain more patents to protect Bystolic or patents that would enable it to reformulate Bystolic--a product purportedly "reaching the end of its life cycle." JA 1534 (Compl. ¶ 179). At the time the patent-assignment agreement was consummated in November of 2012, however, Bystolic still had longevity: the '040 Patent was not set to expire until nine years later, in December of 2021, and no generic Bystolic was set to launch until three months before that. Plaintiffs further claim that Forest did not publicly disclose plans to develop a reformulated Bystolic using the assigned patents or attribute a specific value to them in its public filings. Forest's alleged lack of disclosures is unavailing absent any plausible allegation that Forest was required to make them or would be likely to announce its plans. The $17 million (maximum) that Forest agreed to pay for the assigned patents was likely immaterial in the grand scheme of its business: Forest was acquired for $25 billion barely a year after it settled its patent litigation with Torrent.[13]

Alkem and Indchemie. Forest entered into a term sheet with both Alkem

[13] The allegations underscore the relative modesty of Forest's investment into the Torrent patents. The Complaint points out that, just months before it entered into the patent-assignment agreement, Forest purchased Bystolic's U.S. patents and IP for $357 million, some twenty times the amount Forest paid for the assigned patents.

and Indchemie (together, "Alkem") governing a contemplated supply agreement for two finished drug products: Bystolic (nebivolol) and Byvalson (nebivolol and valsartan). Under the term sheet, Alkem would supply Forest with at least 45% of Forest's annual Bystolic and Byvalson requirements in the U.S. and Canada. Forest was allegedly required to pay Alkem at least $20 million--including contingent milestone payments of $1 or $1.5 million aggregating up to $13 million for "[d]evelopment [w]ork" pertaining to Bystolic and Byvalson. JA 854–55.

Plaintiffs again take aim at several particular provisions of this Commercial Transaction. They contend that, at the time Forest consummated the supply agreement with Alkem, Forest was already producing a sufficient amount of Bystolic to satisfy market demand; that neither the FDA website nor any other public source identified Forest as having any supply shortages for finished Bystolic; and that the term sheet does not mention any manufacturing issues or need for a backup manufacturer. These allegations constitute speculation and conjecture; even assuming they may be "consistent with the conclusion that [Defendants] violated the law," more is needed to "actively and plausibly suggest that conclusion." Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 121 (2d Cir. 2007). Again, Forest's decision to obtain another source of finished

Bystolic was consistent with what it disclosed to investors in its 10-K: that its manufacturing facilities in Ireland are the "exclusive qualified manufacturing facilities" for finished Bystolic, and that "[d]ifficulties or delays in the product supply chain" or the inability to timely "locate and qualify third party alternative sources" may cause "shortages or long-term product unavailability." JA 1161. As to Byvalson, the Complaint describes it as a "new combination product" (nebivolol and valsartan) for which Forest had not yet submitted a NDA. JA 1535–36 (Compl. ¶¶ 182–83). But Forest could not have submitted the Byvalson NDA without information about its manufacture. See 21 U.S.C. § 355(b)(1)(A)(iv) (NDA must include "a full description of the methods used in, and the facilities and controls used for, the manufacture . . . of [the] drug.").

Plaintiffs point that the term sheet required Forest to reimburse Alkem for costs and expenses incurred for "[d]evelopment [w]ork," JA 856, in connection with Bystolic and Byvalson; and assert that this constituted double counting because the term sheet also required Forest to pay Alkem up to $13 million for "development work" milestones. The term sheet, however, provided for two distinct payments to Alkem: (i) reimbursement for costs and expenses in connection with development work (pursuant to a "mutually agreed work-plan

and budget"), JA 856, and (ii) up to $13 million for milestones achieved as part of that work. There is nothing duplicative about lump-sum rewards for cleared benchmarks and variable compensation for the underlying work.

The Complaint further claims that Forest agreed in the term sheet to pay Alkem up to a 10% premium over prices available from other suppliers. That misreads the applicable provision, which functioned as a price cap that protected Forest against the possibility of a large price hike. The supply agreement was to run for a five-year term, plus two automatic, successive one-year renewal periods conditioned on, among other things, Alkem's willingness and ability to supply Bystolic and Byvalson at a competitive price--defined as one "not more than 10% higher than prices generally available" from other comparable sources. JA 852. Far from being a windfall for Alkem, the provision was a means for Forest to *limit* its future purchase price (while still allowing for a reasonable price increase) and promote competition--rather than "prevent" it. Actavis, 570 U.S. at 157.

Plaintiffs add that, contrary to typical industry practice, the term sheet provided that only after its execution would Alkem permit Forest to conduct due diligence on the manufacturing facilities or send Forest its FDA inspection reports. These terms are unremarkable when the term sheet is considered "as a

whole," as it must be. Int'l Klafter Co. v. Cont'l Cas. Co., 869 F.2d 96, 99 (2d Cir. 1989). The term sheet constituted a preliminary, condensed set of terms intended to govern a supply agreement "to be entered into" by Forest and Alkem.[14] JA 852. It was "only natural," Twombly, 550 U.S. at 566, that in settling their patent litigation, Forest and Alkem would decide to prioritize the preparation of a term sheet over diligence that would take place "[p]romptly" after the term sheet was signed, JA 856. In any event, diligence was not ignored; it would include, for example, a "customary Quality Agreement" for manufacturing and control, and inspections of manufacturing facilities by Forest personnel. JA 856.

Glenmark. Forest and Glenmark entered into a collaboration-and-option agreement pursuant to which they would jointly develop molecular inhibitors of microsomal prostaglandin e synthase-1 ("mPGES-1"). Forest was to leverage Glenmark's "experience in the research and development of proprietary compounds, compositions and methods," as well as its "know-how" regarding the discovery of mPGES-1 inhibitors. JA 1000. If the collaboration succeeded, Forest stood to gain a major financial benefit through an optional, sole right of

[14] No such final agreement is in the record.

first negotiation for an exclusive licensing agreement with Glenmark, pursuant to which Forest would develop and commercialize mPGES-1 products.

The collaboration-and-option agreement contemplated Glenmark performing the development work subject to strong oversight from Forest through a Joint Development Committee ("JDC"). The JDC would have quarterly meetings and duties ranging from monitoring the progress of the mPGES-1 development work and providing recommendations as to additional development work. Among other information about the joint development project, Glenmark was required to furnish Forest with quarterly progress reports and clinical research data for Forest to review or raise with the JDC, as well as an advance copy of any publication of pre-clinical and clinical-trial results.

The collaboration-and-option agreement required Forest to pay Glenmark $15 million--including $9 million upfront, comprising $6 million for Forest's option rights and prior R&D expenses, as well as a $3 million advance for R&D expenses to be incurred over the first nine months of the agreement's twenty-seven-month term. The remaining $6 million consisted of research-fee payments: a $2 million advance after nine months for R&D services to be performed over the subsequent six months, and a $4 million advance after fifteen

months (or six months after the prior $2 million payment) for R&D undertaken during the ensuing year.

The Complaint takes futile issue with several aspects of the collaboration-and-option agreement. Plaintiffs contend that no public source suggests Forest expressed any interest in Glenmark's development of mPGES-1 before entering into this agreement. But Plaintiffs fail to explain why this information would be public; they identify neither a duty for Forest to disclose it, nor a rational business reason for it to do so absent such a duty. The only plausible inference is that Forest agreed to deal with Glenmark because it sought to pursue the development of mPGES-1 products. Forest made this inference explicit in its Form 10-K, which stated that Forest's suite of products included "those developed in conjunction with our partners." JA 1163.

Plaintiffs point out that the December 2012 collaboration-and-option agreement was structured differently from a collaboration agreement that Forest and Glenmark had entered into in 2004 concerning Glenmark's PDE4 inhibitor GRC 3886. Although the 2004 deal is not in the record, Plaintiffs cite a news article that reported on it. According to the Complaint, this agreement "unambiguously defined what each of Forest and Glenmark got from the

agreement" and was unrelated to settling patent litigation. JA 1538–39 (Compl. ¶ 190). The differences between the 2004 collaboration agreement and the 2012 collaboration-and-option agreement, Plaintiffs posit, suggest that the latter was used merely as a way for Forest to pay Glenmark to stay out of the nebivolol market.

But the Complaint merely asserts that the two agreements are "different" without explaining why this matters, or why the 2004 agreement is an appropriate comparator. For example, there is no allegation that the Glenmark PDE4 inhibitor GRC 3886 contemplated by the 2004 agreement was similar to the mPGES-1 inhibitor contemplated by the collaboration-and-option agreement. Even assuming similarity, the Complaint does not explain why any such differences between the agreements point to nefarious motives. We are not aware of any presumption that, once two parties enter into a contract on one subject, any of their future contracts on that subject are bound to follow the same terms and price structure. If anything, the parties' history of dealings with each other makes it less likely that Forest's agreement with Glenmark was merely a pretext for anticompetitive conduct.

Moreover, the alleged differences between the 2004 and 2012

Forest-Glenmark agreements do not assist the Plaintiffs. According to the news report cited in the Complaint, one of the 2004 agreement's provisions was "an up-front payment upon initiation of the agreement, and other milestones if the development and commercialization of the product was successfully completed in the North American market." JA 1539 (Compl. ¶ 190). The 2012 payment terms were not suspicious by comparison, but rather reflected similar incentives: they were proportionally distributed, i.e., $1 million for every three months of R&D; could be accelerated based on important milestones (in a manner similar to the 2004 agreement), i.e., Glenmark's filing of an investigational new drug application and Forest's receipt of specified data from Glenmark; and covered expenses crucial to the object of the agreement, i.e., the development of a mPGES-1 inhibitor. If these R&D expenses helped produce a marketable product, Forest stood to obtain a major financial benefit through a valuable licensing agreement with Glenmark--the same incentive animating the 2004 agreement's similar payment structure.

Finally, the Complaint seizes on the exclusive option rights that the collaboration-and-option agreement granted to Forest. Plaintiffs allege that the only "right" Forest obtained was a right of first negotiation that the parties valued

at less than $6 million, and pursuant to which Forest obtained only the "right to attempt to negotiate a deal" with Glenmark. JA 1540 (Compl. ¶ 191). But there is nothing sinister about one party paying another for an exclusive right to negotiate a lucrative agreement--one that, in this instance, would allow Forest to capitalize on Glenmark's experience and know-how in developing the product at issue, and would represent the culmination of a collaboration that Forest steered and into which Forest poured considerable time and expense.[15]

Amerigen. Forest and Amerigen entered into a term sheet for a collaboration agreement, under which Forest would pay Amerigen for the development of eight "US Products": three "[i]nitial" and five "[a]dditional" ones. JA 1109–10. Forest would make a $5 million payment upfront, as well as milestone payments of up to $20 million contingent on developments such as the completion of clinical bioequivalence studies, the FDA's acceptance for filing of an ANDA for a US Product, and the first commercial sale of such products.

[15] Plaintiffs also point out that if Forest and Glenmark failed to reach an agreement during their 120-day negotiating window, Glenmark could choose to deal with a third party, unless the deal was "materially more favorable" to the third party than the terms offered to Forest. JA 1540 (Compl. ¶ 191). This provision benefited Forest by allowing it--over a nine-month period--to ensure Glenmark was offering Forest the best available deal by effectively blocking Glenmark from entering into more favorable deals with other developers.

Amerigen agreed to pay Forest specified percentages of gross margin (ordinarily 20%) as royalties for sales of the US Products. If Amerigen failed to commercialize at least one US Product within five years, Forest could terminate the term sheet as to all US Products and recover all milestone payments; otherwise, Forest's right of termination was limited to products for which specified developmental objectives had not been met, with recovery of 50% of milestone payments. Thus, Forest was expressly authorized to recoup its (allegedly unlawful) reverse payment to Amerigen. Separately, Forest received an option to exclusively market and commercialize up to eight Amerigen products in Latin America.

The Complaint identifies details of the term sheet that it views as suspicious, without explaining why such features support the conclusion that these arrangements were anything other than an exchange of fair value for services reflecting Forest's own, lawful "business priorities." Citigroup, 709 F.3d at 138. Plaintiffs contend that Forest "did not truly care" whether the US Products fit into its portfolio, JA 1542 (Compl. ¶ 197), given that the term sheet allowed Amerigen to discontinue the development of these products so long as (among many other conditions described below) it proposed a minimum of two

"alternate products that are of similar value taken as a whole" relative to each discontinued product, JA 1116–17. That misconstrues the term sheet. Amerigen's discontinuation right was subject to several qualifications granting Forest considerable control over both the discontinuation process and the substitute products:

- Amerigen could seek to discontinue only products that it believed were "no longer technically or commercially viable";
- to do so, Amerigen needed to provide Forest with a "Discontinuation Notice," i.e., a written explanation including a detailed description of why Amerigen decided that such a product was no longer viable and should be discontinued;
- at Forest's request, the parties were required to "promptly" meet (i.e., within five business days of Forest's request) to discuss the proposed discontinuation, and Amerigen was required to "give reasonable consideration to Forest's comments regarding whether or not to discontinue the development of such US Product";
- only after this meeting, and not until thirty days after Forest received the Discontinuation Notice, could Amerigen discontinue the product in question;
- even then, discontinuation was contingent on Amerigen providing Forest with a written "Substitution Notice" proposing at minimum two alternative products "of similar value" for the discontinued product, "taking into account probability of technical success, time to commercial launch and commercial potential"; and
- within thirty days of receiving the Substitution Notice, Forest would

> choose one of the substitution products to replace the discontinued product.

JA 1116–17. Contrary to Plaintiffs' suspicions, the relevant provisions reflect that Forest was deeply invested in both the type and nature of products it was investing in as well as their potential substitutes, which were required to be of similar value.

Plaintiffs also observe that, even though the term sheet contemplated the parties negotiating a definitive collaboration agreement "[i]mmediately" after the term sheet's execution, JA 1109, the parties' agreement is dated June 9, 2014--nearly a year after the term sheet's effective date. This later date, Plaintiffs add, fell only weeks after Forest received a civil investigative demand ("CID") from the FTC concerning its settlements with the Generic Defendants. According to Plaintiffs, this timing suggests that the collaboration agreement was executed chiefly as protection against antitrust liability.

But Twombly's plausibility requirement, though not equivalent to a "probability requirement, . . . asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678 (internal quotation marks omitted). Forest entered into the term sheet well before it received the

CID; the term sheet expressly anticipated subsequent negotiation of a definitive collaboration agreement; and the Complaint offers no reason to infer that it was unusual or improper for these negotiations to last close to one year. The term sheet expressly anticipated that the negotiations might be prolonged by providing that the parties would remain bound by it if they failed to reach a final agreement within 120 days. Plaintiffs' suspicion is indiscriminate: at the same time suspicion is roused by how long Forest took to finalize the Amerigen agreement, it is also roused by the idea that Forest's contracts with other Generic Defendants were "rush job[s]."[16] JA 1531, 1537 (Compl. ¶¶ 170, 185).

Watson. Plaintiffs contend that Forest made an unlawful reverse payment to Watson via two separate transactions:

- (1) Forest entered into a letter agreement with Moksha8--a pharmaceutical company that commercializes products in Brazil and Mexico. The agreement acknowledged that Moksha8 had materially breached three

[16] Plaintiffs point out that, at the time Forest and Amerigen entered into the term sheet, Forest "publicly represented itself to be a specialty pharmaceutical company marketing 'branded' drug products," whereas the five "[a]dditional" US Products were generics, which were outside of "Forest's stated focus." JA 1541–42 (Compl. ¶ 197). Plaintiffs do not explain their apparent theory that pharmaceutical companies can only invest in products that they publicly proclaim to "specialize" in or "focus" on. Such a premise is not based in common sense or business logic, but rather constitutes another instance of straw-grasping.

loan-and-security agreements with Forest, relieving Forest of the need to extend additional loans to Moksha8. Forest nevertheless undertook to provide Moksha8 with roughly $7 million in credit. In exchange, Forest obtained a broad release from claims arising out of the loan-and-security agreements. This letter agreement, therefore, provided for Forest to transfer value to Moksha8--not Watson, the alleged recipient of the illegal reverse payment--in exchange for a broad release.

- (2) Moksha8 entered into a termination-and-release agreement with Watson's successor, Actavis (hereinafter "Watson"). Watson and Moksha8 agreed to release each other from any obligations or liabilities arising from (a) specified prior agreements entered into by Watson and Moksha8, among other parties, and (b) a prior merger agreement among Forest, Moksha8 and another entity (and terminate the former set of agreements). Finally, Watson--not Forest--agreed to pay Moksha8 $4 million.

Plaintiffs claim that Forest's letter agreement with Moksha8, in conjunction with the termination-and-release agreement between Moksha8 and Watson, effected a roundabout payment to Watson of $15 million or more in order to delay its launch of generic Bystolic. In particular, Plaintiffs contend that the releases Moksha8 granted to Watson pursuant to their termination-and-release agreement were worth at least $15 million more than the $4 million Watson agreed to pay Moksha8--and thus at least $19 million in total. It is alleged that Forest somehow paid Moksha8 to make up the difference, although Plaintiffs admit that they "cannot tell precisely how Forest used the transaction with Moksha8 to transfer

this payment to Watson." JA 1547 (Compl. ¶ 215). We can't either.

These allegations are at once complicated and threadbare. As Plaintiffs concede, the means of payment is a mystery. They make no attempt to explain how Forest's $7 million *loan* to *Moksha8*--which is not a party to this case and was not involved in the Nebivolol Patent Litigation--was used to effect a $19 million *payment* to *Watson*. Plaintiffs' allegations for the other alleged side deals at least pointed to payments that Forest expressly contracted to make to the Generic Defendants. Here, the most Plaintiffs muster is a conclusory claim that there is a "clear inference" Forest used the letter agreement with Moksha8 to pay off Watson. JA 1547 (Compl. ¶ 215); see also Appellants' Br. 58 (conceding they failed to plead "how value was transferred from Moksha8 to Watson"). Even assuming that the Complaint pleads a reverse payment, full stop, there is no plausible basis to conclude that either of the two agreements--whether considered alone or together--somehow effected an "unjustified" one.

* * *

For the foregoing reasons, we **AFFIRM** the district court's judgment dismissing Plaintiffs' claims with prejudice.[17]

[17] Because there is no dispute that all of Plaintiffs' federal and state claims are based on the same underlying conduct, they all fall together.

United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

DEBRA ANN LIVINGSTON
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: May 13, 2024
Docket #: 23-410cv
Short Title: In re Bystolic Antitrust Litigation

DC Docket #: 20-cv-5735
DC Court: SDNY (NEW YORK CITY)
DC Judge: Liman

BILL OF COSTS INSTRUCTIONS

The requirements for filing a bill of costs are set forth in FRAP 39. A form for filing a bill of costs is on the Court's website.

The bill of costs must:
* be filed within 14 days after the entry of judgment;
* be verified;
* be served on all adversaries;
* not include charges for postage, delivery, service, overtime and the filers edits;
* identify the number of copies which comprise the printer's unit;
* include the printer's bills, which must state the minimum charge per printer's unit for a page, a cover, foot lines by the line, and an index and table of cases by the page;
* state only the number of necessary copies inserted in enclosed form;
* state actual costs at rates not higher than those generally charged for printing services in New York, New York; excessive charges are subject to reduction;
* be filed via CM/ECF or if counsel is exempted with the original and two copies.

United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

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VERIFIED ITEMIZED BILL OF COSTS

Counsel for

_____

respectfully submits, pursuant to FRAP 39 (c) the within bill of costs and requests the Clerk to prepare an itemized statement of costs taxed against the

_____

and in favor of

_____

for insertion in the mandate.

Docketing Fee _____

Costs of printing appendix (necessary copies _____) _____

Costs of printing brief (necessary copies _____ ____) _____

Costs of printing reply brief (necessary copies _____) _____

(VERIFICATION HERE)

_____
Signature