UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BYSTOLIC ANTITRUST LITIGATION

20-cv-5735 (LJL)

OPINION AND ORDER

LEWIS J. LIMAN, United States District Judge:

On January 24, 2022, this Court dismissed without prejudice Direct Purchaser and Retailer Plaintiffs' Second Amended Complaints and End-Payor Plaintiffs' First Amended Complaint (collectively, "Prior Complaints"),[1] together alleging that Defendants engaged in an illegal scheme to delay competition from generic versions of Bystolic (nebivolol hydrochloride), a drug used to treat high blood pressure, in violation of the Sherman Act, 15 U.S.C. § 1 *et seq*., and state antitrust and consumer protection laws.[2] Dkt. No. 350; Dkt. No. 354 ("January 2022

[1] The "Direct Purchaser Plaintiffs" ("DPP") are J M Smith Corporation d/b/a Smith Drug Company and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc., on behalf of themselves and all others similarly situated. The "Retailer Plaintiffs" are CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Walgreen Co., The Kroger Co., Albertsons Companies, Inc., and H-E-B, L.P. The "End-Payor Plaintiffs" ("EPP") are the 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, on behalf of themselves and all others similarly situated. Together, they are referred to as "Plaintiffs."

[2] Defendants include the manufacturers and marketers of Bystolic ("Forest") and their generic-drug competitors ("Generic Defendants"). "Forest" refers collectively to: Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd.; AbbVie, Inc.; and Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. "Generic Defendants" refers collectively to: Hetero USA Inc., Hetero Labs Ltd., and Hetero Drugs Ltd. (collectively, "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

Opinion"). Direct Purchaser Plaintiffs subsequently filed a Third Amended Complaint ("DPP Complaint"), Retailer Plaintiffs filed Third Amended Complaints ("Retailer Plaintiffs' Complaints"), and End-Payor Plaintiffs filed a Second Amended Complaint ("End-Payor Plaintiffs' Complaint") (collectively, "Complaints"), in an attempt to redress the gaps that the Court previously identified in the Prior Complaints. Dkt. Nos. 426, 427.[3]

Defendants have filed four motions to dismiss the Complaints. All Defendants move to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. No. 393. All Defendants also move to dismiss End-Payor Plaintiffs' Complaint for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. No. 397. Defendant Teva Israel moves pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction. Dkt. No. 388. Finally, a group of Defendants allegedly not at home in New York ("Nonresident Defendants")[4] move pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss for lack of personal jurisdiction the EPP Complaint's non-New York, state-law claims. Dkt. No. 386.

(collectively, "Torrent"); Ascend Laboratories, LLC and Alkem Laboratories Ltd. (collectively, "Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA, Glenmark Generics Ltd., Glenmark Pharmaceuticals Ltd., and Glenmark Pharmaceuticals S.A. (collectively, "Glenmark"); ANI Pharmaceuticals, Inc., Amerigen Pharmaceuticals, Inc., and Amerigen Pharmaceuticals, Ltd. (collectively, "Amerigen"); Teva Pharmaceuticals Industries Ltd. ("Teva Israel"); Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., Watson Pharmaceuticals Inc., Actavis, Inc., and Teva Pharmaceuticals USA, Inc. (collectively with Teva Israel, "Watson"). Forest and Generic Defendants are collectively referred to as "Defendants."

[3] Retailer Plaintiffs filed their third amended complaints in the related cases of *CVS Pharmacy, Inc. et al v. AbbVie Inc. et al*, 20-cv-10087 (S.D.N.Y.), ECF No. 43, and in *Walgreen Co. et al v. AbbVie Inc. et al*, 20-cv-9793 (S.D.N.Y.), ECF No. 47.

[4] Nonresident Defendants include all Defendants except for Watson Laboratories, Inc. (NY), Forest Laboratories, Inc., and the latter's successors—Forest Laboratories, LLC and Allergan Sales, LLC.

For the following reasons, Defendants' motions to dismiss the Complaints pursuant to Federal Rule of Civil Procedure 12(b)(6) are granted and the Complaints are dismissed with prejudice. The motions to dismiss based on a lack of personal jurisdiction are denied as moot.

BACKGROUND

Familiarity with the facts and the Hatch-Waxman regulatory framework for the approval of generic equivalents of branded drugs is presumed. On each of the four motions to dismiss, the Court accepts as true the factual allegations of the Complaints and the documents incorporated therein by reference.[5] The Court first briefly summarizes the alleged scheme and then describes the general terms of the Agreements. In the Discussion section, the Court reiterates the principal holdings from the January 2022 Opinion and discusses whether any new allegations in the Complaints address the shortcomings that the Court identified in the Prior Complaints.

I. Overview of the Alleged Scheme

Forest manufactures Bystolic, a "beta blocker" approved by the U.S. Food and Drug Administration ("FDA") to treat high blood pressure that generates nearly $1 billion in annual sales in the United States. Dkt. No. 427 ¶ 1.[6] Bystolic is the brand name of a drug otherwise known as nebivolol hydrochloride or nebivolol HCl. *Id*. at ECF p. 1; *id.* ¶ 122. Nebivolol itself is a mixture of two "stereoisomers," which are different configurations of the structure of a

[5] Because the Complaints refer extensively to the agreements between the Defendants ("Agreements") and their effects, the Court may consider them on a motion to dismiss. *See Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 196 (2d Cir. 2005) ("Where a plaintiff has 'rel[ied] on the terms and effect of a document in drafting the complaint,' and that document is thus 'integral to the complaint,' [the court] may consider its contents even if it is not formally incorporated by reference." (alteration in original) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002))).

[6] This opinion cites to the DPP Complaint as the other Plaintiffs' complaints are substantially identical.

chemical compound. *Id*. ¶¶ 120–21. As the source of the desired pharmacological effects, nebivolol constitutes the active pharmaceutical ingredient ("API") of Bystolic. *Id*. ¶ 122.

In December 2011, Generic Defendants, seeking FDA approval for manufacture of generic versions of Bystolic, filed Abbreviated New Drug Applications ("ANDAs") with Paragraph IV certifications. Those certifications provide that the underlying Bystolic patents are "invalid or will not be infringed by the generic manufacturer's proposed product." *Id*. ¶ 99. Forest subsequently filed patent infringement lawsuits against Generic Defendants ("Nebivolol Patent Litigation"). Under the Hatch-Waxman regulatory framework, the filing of those lawsuits delayed FDA approval of the ANDAs by a period of time not to exceed thirty months.

From October 2012 through November 2013, Forest entered into a series of reverse-payment deals (described by Plaintiffs as "pay for delay" deals) with Generic Defendants described in more detail below. Among other things, in connection with the settlement of the Nebivolol Patent Litigation, each Generic Defendant (1) agreed not to compete with Forest or enter the market with its generic version of Bystolic prior to September 17, 2021 (three months before patent expiration), unless another Generic Defendant entered that market earlier; and in exchange, (2) received cash payments from Forest; and (3) entered into "side deals" with Forest. *Id*. ¶ 3. Plaintiffs allege that those "side deals" had the intent and effect of allowing Forest to maintain its monopoly profits from the sale of Bystolic and delayed the entry of less expensive generic forms of Bystolic. *Id*. ¶¶ 2, 3.

Plaintiffs' factual allegations in the Complaints generally mirror their allegations in the Prior Complaints. The introduction and sections on the regulatory background—including the descriptions of the regulatory approval process of generic drugs, the competitive effects of generic competition, and the financial incentives for brand and generic companies to agree to

anticompetitive terms—remain unchanged in the Complaints. *See id.* ¶¶ 1–114. Plaintiffs also reiterate the point which was clear from the Prior Complaints—that "each side deal was entered into contemporaneously with the settlement of the Nebivolol Patent Litigation and the Generic Defendants' agreement to delay generic entry." *Id.* ¶ 158. Plaintiffs, citing *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), further reiterate that each side deal provided payments to each generic manufacturer with first-filer exclusivity "even though none of them had any claim to damages as a result of the Nebivolol Patent Litigation." Dkt. No. 427 ¶¶ 159–60.[7]

Plaintiffs, citing a law review article, also add several paragraphs to their Complaints describing what they allege to be the "history of reverse payments." *See id.* ¶¶ 154–57 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629 (2009)). Those paragraphs allege that "the earliest reverse payments were naked cash payments to compensate generic companies for delaying generic entry," *id.* ¶ 154, that "as antitrust scrutiny of reverse payments increased, the use of 'side deals' to disguise reverse payments has become common," *id.*, that the "most common type of 'side deal' involves the brand company overpaying the generic company for a product or service provided by the generic company, via a patent license, supply of raw materials, manufacturing, product development or co-promotion agreement," *id.* ¶ 155, and that "outside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals," *id.* ¶ 157 (citation omitted). The paragraphs and article otherwise do not discuss the Agreements or Defendants' conduct.

[7] Plaintiffs also allege that "Forest has a history of using side deals," citing Forest's outside and in-house counsel's usage of the term "side deal" with respect to a separate patent dispute involving Namenda, "another of Forest's blockbuster products." *Id.* ¶ 161. Plaintiffs further rely on the "Agovino email" to allege that outside and in-house counsel referred to the Agreements as "side deals," but that allegation was included in the Prior Complaints. *See* Dkt. No. 250 ¶ 151.

II. The Agreements

The Agreements alleged by Plaintiffs took different forms and were entered into in different time periods. Each set of agreements included a Settlement Agreement and a License Agreement. The terms of the Settlement Agreements and License Agreements were generally uniform but differed in some respects. For example, some of the License Agreements provided for Forest to reimburse the generic manufacturer for Forest's saved litigation costs and the manufacturer's expended litigation costs up to a specified maximum, while others provided for a fixed payment.

The first agreements alleged by Plaintiffs are Forest's agreements with Hetero, which took the form of a Settlement Agreement and License Agreement dated October 24, 2012 and a Final Term Sheet dated October 5, 2012. *Id.* ¶ 163. The Settlement Agreement and License Agreement provided that Forest would grant Hetero a non-exclusive license to sell generic Bystolic three months before the patent expired (subject to an earlier launch if a third party commenced a launch at risk), that Forest and Hetero would agree to dismiss all claims and counterclaims asserted against one another in the Nebivolol Patent Litigation and grant each other releases, and that Forest would pay Hetero up to $200,000 for Hetero's expended litigation fees and costs and Forest's saved legal fees in connection with the Nebivolol Patent Litigation. Dkt. No. 270-1. The Final Term Sheet obligated Hetero to sell and Forest to purchase at a fixed price a supply of nebivolol API equal to at least 50% of Forest's requirements for use in manufacturing Bystolic. Dkt. No. 427 ¶ 163; Dkt. No. 270-2. Plaintiffs allege that the Final Term Sheet never resulted in a final supply agreement. Dkt. No. 427 ¶ 170.

Approximately one month later, Forest entered into a Settlement Agreement and License Agreement with Torrent dated November 21, 2012 and a Patent Assignment Agreement of the same date. *Id.* ¶ 176. The Torrent Settlement Agreement and License Agreement contained

similar terms to the Hetero Settlement Agreement and License Agreement, including the terms of the license and the settlement of the Nebivolol Patent Litigation, but also included the requirement that Forest pay Torrent up to $1 million for Torrent's expended litigation fees and costs and Forest's saved legal fees. Dkt. No. 270-12. The Patent Assignment Agreement provided that in exchange for a payment from Forest of up to $17 million, Torrent would sell to Forest ten patents covering compositions and/or manufacturing processes used in the manufacture of nebivolol drug product. Dkt. No. 427 ¶ 176; Dkt. No. 270-13.

Shortly thereafter, Forest entered into agreements dated November 27, 2012 and November 28, 2012 with a third generic manufacturer, Alkem/Indchemie, to settle the Nebivolol Patent Litigation and for Alkem/Indchemie to both license Bystolic and supply Forest with the finished product of two drugs for a period of at least five years. Dkt. No. 427 ¶ 181. Under the Settlement Agreement and License Agreement dated November 27, 2012, in addition to the grant of the license and the dismissal of claims and mutual releases, Forest agreed to pay Alkem/Indchemie a fixed sum of $1 million for Alkem/Indchemie's expended litigation fees and costs and Forest's saved legal fees. Dkt. Nos. 270-7, 270-8. Under a Term Sheet dated November 28, 2012, Alkem/Indchemie agreed to sell to Forest and Forest agreed to purchase, for a payment of "at least $20 million," 45% of its required supply of Bystolic and Byvalson (nebivolol and valsartan) tablets in the United States and Canada for five years with automatic renewal periods of one year each. Dkt. No. 427 ¶ 181; Dkt. No. 270-9.

The following month, Forest entered into agreements with a fourth generic manufacturer, Glenmark. Dkt. No. 427 ¶ 188. The Settlement Agreement and License Agreement between Forest and Glenmark dated December 21, 2012 provided—in addition to the settlement and mutual releases—for Forest to pay Glenmark up to $1.2 million for Glenmark's expended

litigation fees and costs and Forest's saved legal fees and provided Glenmark a license to sell generic Bystolic. Dkt. No. 270-14. A Collaboration and Option Agreement of the same date gave Forest the right to jointly develop microsomal prostaglandin e synthase-1 ("mPEGS-1") products with Glenmark for a period of at least 27 months absent earlier termination and an option right of first negotiation for exclusive commercialization rights of those products. In exchange, Forest made an aggregate payment of $15 million to Glenmark. Dkt. No. 427 ¶ 188; Dkt. No. 270-15.

Over six months later, Forest entered into agreements with a sixth generic manufacturer, Amerigen. The agreements with Amerigen were both dated July 18, 2013. Dkt. No. 427 ¶ 195. The Settlement Agreement and License Agreement provided, in addition to the settlement of the litigation and the releases and the grant of a non-exclusive license to sell generic Bystolic, for Forest to pay $2 million to Amerigen for Amerigen's expended litigation fees and costs and Forest's saved legal fees. Dkt. No. 270-17. A Binding Term Sheet Collaboration Agreement ("Collaboration Agreement") provided for Forest's investment in the development of eight Amerigen products as reflected by a fixed up-front payment of $5 million and $20 million in milestone payments contingent upon certain product development and launch events, and an option for Forest to commercialize up to eight Amerigen products in Latin and South America for which Amerigen would be the supplier. Dkt. No. 427 ¶ 195; Dkt. No. 270-19.

Forest's last set of agreements occurred in November 2013 with Watson. Dkt. No. 427 ¶ 200. In addition to the same terms with respect to settlement, releases, and a non-exclusive license as reflected in the agreements with the other generic manufacturers, the Settlement Agreement and License Agreement dated November 6, 2013 between Forest and Watson

entities[8] required Forest to pay up to $2 million for Watson's expended litigation fees and costs and Forest's saved legal fees. Dkt. No. 270-4. A Letter Agreement dated November 1, 2013 between Forest and Moksha8 committed Forest to extend approximately $7 million in additional "Term C" loans in exchange for releases to Forest from Moksha8 and other parties. Dkt. No. 270-5. Finally, a Termination and Release Agreement dated November 1, 2013 between Actavis and Moksha8 terminated a series of agreements between Watson and Moksha8 entered into from 2010 to 2012, and released each other from any obligations arising from those agreements, as well as obligations in any way related to transactions contemplated by an Agreement and Plan of Merger, dated October 22, 2012, by and among Forest, M8 Holdings LLC, and Moksha8 Parent (the "Merger Agreement"), or any agreement contemplated by the Merger Agreement. Dkt. No. 427 ¶ 200; Dkt. No. 270-6.

In all, Forest agreed to pay a total of up to $7.4 million to the six generic manufacturers for the expended litigation costs of each of those manufacturers and the saved legal fees of Forest in connection with the patent litigation over a drug alleged to generate nearly $1 billion in annual sales in the United States. As befitting the settlement of litigation, those generic manufacturers with whom Forest settled later, and thus who presumably incurred more expenses, were paid more than the generic manufacturers who settled earlier. At the same time, Forest entered into side deals with each of the manufacturers pursuant to which it made payments that totaled close to $100 million in exchange for a variety of different rights from each manufacturer. Dkt. No. 427 ¶ 142. Forest also provided each generic manufacturer a license to sell generic Bystolic three months before patent expiration. Finally, each agreement contained a "contingent launch"

[8] Those Watson Entities included Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc.

provision that accelerated the launch date to the date that any other generic manufacturer launched, if any of the other generic manufacturers launched earlier than the three months before patent expiration.

The upshot of the settlements is that Forest was able to continue to exploit the monopoly its patent gave over Bystolic past any FDA approval of Generic Defendants' ANDAs on June 18, 2015 (or an earlier favorable decision in the patent suit for Generic Defendants) until September 17, 2021, which is three months before the patent would have expired. The further upshot is that each of the generic manufacturers were able to market generic Bystolic three months earlier than they otherwise would have had the rights to do so, had those manufacturers lost the Nebivolol Patent Litigation. The principal question in this case is whether those Agreements constitute impermissible pay-for-delay agreements in violation of the federal antitrust laws.

PROCEDURAL HISTORY

The first actions in this case were filed in July 2020. Direct Purchaser Plaintiffs and Retailer Plaintiffs first brought claims for damages under federal antitrust law. End-Payor Plaintiffs then brought claims under state antitrust and consumer-protection laws and for injunctive relief under federal antitrust law. The Direct Purchaser Plaintiffs' actions were consolidated, the End-Payor Plaintiffs' actions were consolidated, and the two consolidated actions and the two Retailer Plaintiffs' actions were coordinated with one another under one docket to promote efficiency in managing and litigating the cases. Dkt. Nos. 50, 82, 86, 204; *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 19; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 20. Defendants moved to transfer the cases to the District of New Jersey, Dkt. No. 79, but the Court denied the motion to transfer venue, Dkt. No. 178.

On December 3, 2020, Direct Purchaser Plaintiffs filed their Consolidated and Amended Class Action Complaint, Dkt. No. 111, and End-Payor Plaintiffs filed their Consolidated Class

Action Complaint, Dkt. No. 113. On December 23, 2020, Retailer Plaintiffs filed their respective amended complaints. *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 20; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 21.

Thereafter, Nonresident Defendants moved to dismiss the End-Payor Plaintiffs' complaint for lack of personal jurisdiction, Dkt. No. 215; Teva Israel moved to dismiss all claims against it for lack of personal jurisdiction, Dkt. No. 218; Defendants moved to dismiss Direct Purchaser and Retailer Plaintiffs' complaints for failure to state a claim, Dkt. No. 223; and Defendants moved to dismiss End-Payor Plaintiffs' complaint for failure to state a claim, Dkt. No. 226. In response to Defendants' various motions to dismiss, all Plaintiffs elected to amend their complaints, Dkt. No. 240, and the Court denied the motions to dismiss without prejudice as moot, Dkt. No. 241.

On March 15, 2021, the Prior Complaints in this case were filed: the DPP Prior Complaint, Dkt. No. 250; the Retailer Plaintiffs' Prior Complaints, *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 35; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 34; and the EPP Prior Complaint, Dkt. No. 251. On April 23, 2021, Defendants moved to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints, Dkt. No. 267, and moved to dismiss End-Payor Plaintiffs' Complaint, Dkt. No. 271. That same day, Defendant Teva Israel moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction, Dkt. No. 260, and the Nonresident Defendants moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss for lack of personal jurisdiction the EPP Complaint's ninety-nine non-New York, state-law claims, Dkt. No. 265. After the four motions to dismiss the Prior Complaints were fully briefed, the Court held oral argument on the motions on December 14, 2021. Dkt. No. 343. On January 24, 2022, the Court granted the motions to dismiss the Direct

Purchaser, Retailer, and End-Payor Plaintiffs' Prior Complaints for failure to state a claim without prejudice and denied the motions to dismiss for lack of personal jurisdiction without prejudice as moot. Dkt. Nos. 350, 354.

On February 22, 2022, the Complaints were filed: the DPP Complaint, Dkt. No. 427; the Retailer Plaintiffs' Complaints, *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 43; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 47; and the EPP Complaint, Dkt. No. 426. On April 19, 2022, Nonresident Defendants moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss for lack of personal jurisdiction the End-Payor Complaint's non-New York, state-law claims, Dkt. No. 386, Defendant Teva Israel moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction, Dkt. No. 388, all Defendants moved to dismiss Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), Dkt. No. 393, and all Defendants moved to dismiss End-Payor Plaintiffs' Complaint for a lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), Dkt. No. 397. On May 5, 2022, the New Civil Liberties Alliance and the International Center for Law and Economics filed an amicus brief. Dkt. Nos. 403–405. After the four motions to dismiss were fully briefed, the Court held another oral argument on the renewed motions on November 3, 2022. Dkt. No. 435.

STANDARD OF REVIEW

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, a complaint must include "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570

(2007)). A complaint must offer more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertion[s]" devoid of "further factual enhancement" in order to survive dismissal. *Twombly*, 550 U.S. at 555, 557. The ultimate question is whether "[a] claim has facial plausibility, [i.e.,] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Put another way, the plausibility requirement "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence [supporting the claim]." *Twombly*, 550 U.S. at 556; *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011).

DISCUSSION

Defendants argue that the Complaints failed to cure the deficiencies the Court identified in the Prior Complaints in its January 2022 Opinion. They argue, *inter alia*, that the Complaints failed to add sufficient factual allegations to state a plausible claim that each of the payments were "unjustified" under *Actavis*.

The Court first summarizes its January 2022 Opinion and then addresses the putatively new facts asserted to remedy the flaws in the Prior Complaints.

I. The Court's Prior Opinion and Order

The Court's prior opinion closely analyzed the Supreme Court's decision in *FTC v. Actavis*, 570 U.S. 136 (2013), and surveyed the case law that followed that seminal decision both in this Circuit and elsewhere. *See* Dkt. No. 354 at 16–27.

As noted in the January 2022 Opinion, the Supreme Court in *Actavis* held that antitrust cases premised on reverse-payment settlements of patent litigation—"reverse," because the

settlement required the patentee plaintiff to pay the alleged infringer rather than the other way around—can sometimes violate the antitrust laws and must be evaluated under the rule of reason. *Id*. at 16 (citing *Actavis*, 570 U.S. at 140, 159).

The *Actavis* Court rejected the argument that any agreement pursuant to which a generic manufacturer agreed to honor a patent and to refrain from entering the market prior to the patent's expiration would be presumptively unlawful if the generic manufacturer received payment in exchange for that promise. The Court stated that "a valid patent excludes all except its owner from the use of the protected process or product," *Actavis*, 570 U.S. at 147 (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) (alterations and emphasis omitted)), and that the "exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product," *id.* The *Actavis* Court also recognized "the value of settlements," supported by "traditional settlement considerations, such as avoided litigation costs" in which the payment reflects "a rough approximation of the litigation expenses saved through the settlement," *id.* at 153–54, 156, and that "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition," *id.* at 154. The Court also recognized that "payment may reflect compensation for other services that the generic has promised to perform." *Id.* at 156. A rule that such agreements were presumptively unlawful would deter many agreements that enhanced consumer welfare and would, in effect, inappropriately place the burden on a defendant to prove that any money that changed hands was for something other than delay, such as the generic manufacturer's provision of property or services unrelated to the brand manufacturer's monopoly. *Id.* at 158–59.

At the same time, the Supreme Court also rejected the argument that agreements to settle patent litigation for a reverse payment could never be subject to antitrust scrutiny. An agreement

to settle litigation over the validity of a patent "has the 'potential for genuine adverse effects on competition.'" *Id.* at 153 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460–61 (1986)). If the payment is made by the brand manufacturer to keep the generic manufacturer out of the market and to keep prices at patentee-set levels, "potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger[,] [t]he patentee and the challenger gain; the consumer loses." *Id*. at 154.

The Supreme Court settled on the rule that "[a] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects," noting that "one who makes such a payment may be unable to explain and to justify it." *Id.* at 158. The Supreme Court left it to the "lower courts" to "structur[e] . . . the present rule-of-reason antitrust litigation." *Id.* at 160.[9]

In its January 2022 Opinion, the Court noted the ambiguity within *Actavis* itself, *see* Dkt. No. 354 at 21 n.9, and acknowledged that "the lower federal courts have struggled with the standards set forth by the Supreme Court," *id.* at 21. Some courts would require the plaintiff to reasonably estimate the value of the settlement terms at the pleading stage (calculating the value of the consideration provided and whether it could be explained by reasons other than the desire to stifle competition) and thereby would make it difficult for any complaint (even presumably

[9] The Court agrees with the argument in the amicus brief from the New Civil Liberties Alliance and the International Center for Law and Economics that the appropriate question is the "net" benefit conferred by the reverse payment and not its gross size *vel non*. Dkt. No. 405 at 11–12. In other words, the court examines the amount of the gross payment less the value of goods and services that the patentee contracted to receive including saved litigation costs. *Id.* at 6. Such a conclusion follows from the Supreme Court's holding that a settlement for saved litigation costs or for other goods and services is not inherently suspect. It also is consistent with the Supreme Court's notion that "[a]n unexplained large reverse payment itself would normally suggest that a patentee has serious doubts about the patent's survival." *Actavis*, 570 U.S. at 157. If the payment reflects fair value for goods or services, it would say nothing about the patentee's belief in the validity of the patent. The motion for leave to file an amicus brief is granted.

one filed by the FTC) to survive a motion to dismiss. *Id*. at 23 (citing *In re Actos End Payor Antitrust Litigation*, 2015 WL 5610752, at *19 (S.D.N.Y. Sept. 22, 2015)). Others would hold that whether a payment is large and unjustified would present "intrinsically fact-based determinations" that could not be addressed on a motion to dismiss, thereby permitting complaints to go forward to discovery without any indicia—other than the fact of a large side agreement—to justify the litigation costs. *Id*. at 24–25 (quoting *Sergeants Benevolent Association Health and Welfare Fund v. Acta Vis, PLC*, 2016 WL 4992690, *14 (S.D.N.Y. Sept. 13, 2016)).

The Court attempted to chart a middle course—one that would neither require so much detail at the pleading stage as to "permit many anticompetitive agreements to go unprosecuted and . . . render *Actavis* and the Sherman Act's protection against pay-for-delay agreements an empty promise," *id.* at 27, but one that at the same time required the pleader to allege more than simply "the approximate amount of a payment and that it is large and unjustified in order to state a claim for relief under the general pleading standards of Rule 8 of the Federal Rules of Civil Procedure," *id.* at 25. The Court drew from the Supreme Court's decision in *Twombly* and from the arguments made by the FTC that the Supreme Court rejected in *Actavis*. The Supreme Court in *Twombly* recognized that its decision would allow certain anticompetitive conduct to go unpunished; it "was not oblivious to the fact that 'in antitrust cases, . . . the proof is largely in the hands of the alleged conspirators.'" *Id.* at 28 (quoting *Twombly*, 550 U.S. at 586 (Stevens, J., dissenting)). The Supreme Court concluded, however, that the fact that a complaint's allegations raise the possibility of anticompetitive conduct, without alleging its plausibility, was not sufficient to proceed to discovery. *Twombly*, 550 U.S. at 559; *see also id.* at 556. *Twombly* thus held that "conduct that is consistent with and equally explicable by a pro-competitive

justification—by each defendant acting in its own independent interest—and that raises only the possibility of anticompetitive conduct is not sufficient to state a claim and to subject the defendants to what it characterized as the 'potentially enormous expense of discovery.'" Dkt. No. 354 at 27 (quoting *Twombly*, 550 U.S. at 559).

The Court concluded that, just as in *Twombly*, under *Actavis*, "plaintiffs must show the absence of one or more of the factors that would be consistent with a pro-competitive justification." *Id*. at 29. It would not be sufficient to allege simply the approximate amount of a payment and that it is large and unjustified relative to the consideration exchanged for a complaint to survive a motion to dismiss. The plaintiff "must plead *facts* that would support the claim that the reverse payment was 'large' and 'unjustified,' i.e., that it was not simply possible that the defendants engaged in the anticompetitive conduct of paying the generic manufacturer to forego entering the market but that it was plausible." *Id*. at 30 (emphasis in original).

At the same time, however, the Court rejected the proposition that the only way a complaint could survive a motion to dismiss was to plead the payment that the brand manufacturer made, to calculate the precise value of the consideration it received, and to show that the difference between the two could not be justified by any objective other than to stifle competition. The FTC had argued in *Actavis* that factors other than a discrepancy in value could be relied upon as circumstantial evidence to show that what on its face appeared to be a payment for goods or services was instead large and unjustified and, in fact, a disguised payment to restrain trade. The FTC thus listed factors in addition to whether the amount of the payment "reflected bona fide fair consideration for the property or services":

> whether other terms of the side transaction comported with industry standards; the existence of previous dealings between the parties on the subject matter of the side transaction; a history of demonstrated interest in or need for the property or services

> on the part of the brand-name manufacturer; and the course and content of the manufacturers' negotiations over the agreements.

Id. at 29 (citing Brief for the Petitioner at 37–38, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416)). The Supreme Court rejected the FTC's proposed quick-look approach, which would have placed the burden on defendants as to each of these factors and thus would have relieved the plaintiff of any pleading burden, but it did not reject that such factors—if pleaded by plaintiff—could support a claim under the Sherman Act. *Id*. at 20.

Distilling these considerations, the January 2022 Opinion thus held that to allege facts that a reverse payment is unjustified, a plaintiff:

> might satisfy its pleading burden with facts showing the negative of what the FTC claimed would be evidence of a pro-competitive agreement—e.g., that the terms of the side transaction were not for fair value; that the terms did not comport with industry standards; that there were no previous dealings between the parties on the subject matter of the side transaction; that there was no history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; or that the course and content of the manufacturers' negotiations over the agreements suggested that the purported justification for the agreement was pretextual and that the real reason for the payment was to preserve the brand manufacturer's monopoly.

Id. at 31–32. The plaintiff need not preempt every possible explanation for the reverse payment, but it must plead at least some facts of this nature to sufficiently allege an unjustified agreement. *Id*. at 32 (citing *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 356 (3d Cir. 2020)).

The Court concluded that Plaintiffs had failed to meet this pleading burden. The Court held that Plaintiffs had sufficiently and plausibly alleged that each of the settlement agreements and side agreements were connected to the settlement of the Nebivolol Patent Litigation and were related to one another. *Id.* at 33–34. But it rejected Plaintiffs' argument that it was sufficient that the Prior Complaints alleged large payments and, in a conclusory manner, that the payments exceeded the fair market value of any goods or services to be provided. Such allegations reflected "labels and conclusions" that "could be asserted in every case in which there

is a side agreement with a generic manufacturer who agrees to honor a patent"; if accepted, "there would be nothing left of the Supreme Court's rejection of the per se rule in *Actavis*." *Id.* at 38. Having done so, the Court concluded that Plaintiffs' allegations failed. As to each of the generic manufacturers, Plaintiffs alleged facts that while "consistent with conspiracy," were "just as much in line with a wide swath of rational and competitive business strategy." *Twombly*, 550 U.S. at 554; *see* Dkt. No. 354 at 39.

II. The Alleged Settlement Agreements and Side Agreements

With these considerations in mind, the Court turns to the Complaints. Plaintiffs do not allege that the size of the payments for saved litigation costs and expended litigation fees are themselves large and unjustified and disproportionate. The size of the payments ranged from $200,000 to $2 million and totaled $7.4 million. There is no allegation that they are out of range for the cost of litigation of a major patent lawsuit over a billion dollar product. Rather, Plaintiffs' allegations turn upon the alleged side deals.

Plaintiffs' factual allegations regarding the side deals, however, do not show that they are large and unjustified. In the first instance, neither the allegations that "Forest has a history of using side deals," Dkt. No. 427 ¶ 161, nor the allegation that the "most common type of 'side deal' involves the brand company overpaying the generic company for a product or service provided by the generic company, via a patent license, supply of raw materials, manufacturing, product development or co-promotion agreement," *id.* ¶ 155, is sufficient to "nudge[ ] their claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570. The former allegation cites *In re Namenda Direct Purchaser Antitrust Litig.*, 332 F. Supp. 3d 152, 199 (S.D.N.Y. 2018), a case which later settled. The fact that an allegation was levelled against Forest, however, is not itself a fact from which one can infer that the allegations are true. *Cf. Low v. Robb*, 2012 WL 173472, at *9 (S.D.N.Y. Jan. 20, 2012) ("It is well settled under Second

Circuit law that allegations in a complaint that are either based on, or rely on, complaints in other actions that have been dismissed, settled, or otherwise not resolved, are, as a matter of law, immaterial within the meaning of Fed. R. Civ. P. 12(f)." (internal quotation marks and citation omitted)). More importantly, the claim would have the Court impermissibly infer that just because a prior complaint survived against Forest, that every subsequent complaint must also do so, no matter the deficiencies in its pleading. The latter argument would label every side deal for goods and services anticompetitive and thus 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. Finally, Plaintiffs' allegation that brand manufacturers and generic manufacturers do not typically do business with one another is the type of allegation that might, if it were supported by fact in the circumstances of Forest, be relevant to a *Twombly* analysis. But it is not supported here. The assertion thus assumes the conclusion—that because brand manufacturers do not usually reach agreements with generic manufacturers, the agreements that they reach to cease litigating with one another must be unusual and anticompetitive.

Moreover, when the Court thus turns, as *Twombly* requires, to a "context-specific" review of the Agreements themselves, drawing "on its judicial experience and common sense," *Iqbal*, 556 U.S. at 679, the allegations do not suffice to state a claim. Plaintiffs have not asserted facts as to any of the factors that would suggest conduct inconsistent with a pro-competitive justification. They have not cured the deficiencies identified in the Prior Complaints.

1. Hetero

The allegations in the Complaints with respect to Hetero add little to what was alleged in the Prior Complaints. Forest executed a Settlement Agreement and License Agreement with Hetero on October 24, 2012 that released all of Forest's patent claims, included a payment up to

$200,000 for Hetero's expended litigation fees and Forest's avoided litigation costs, provided a license to Hetero to sell generic Bystolic three months before the patent expired, and required that Hetero not otherwise market or sell generic Bystolic before that date. Dkt. No. 427 ¶ 163; Dkt. No. 270-1. Forest and Hetero also executed a Final Term Sheet for nebivolol API which required Hetero to sell and Forest to purchase a quantity of API equal to at least 50% of Forest's requirements for the United States and Canada at set fixed prices during the minimum five-year term of the supply agreement. Dkt. No. 427 ¶ 163; Dkt. No. 270-2. Plaintiffs approximate payments from Forest to total $37.5 million over that period. Dkt. No. 427 ¶ 163.

In the Prior Complaint, Plaintiffs generally pleaded, on information and belief, that Forest was not in need of API because of its preexisting supply agreement with Janssen and further that in light of that agreement and based on the Term Sheet, the price Forest was paying was excessive. Dkt. No. 250 ¶ 154.[10] Plaintiffs thus asked the Court to infer that because Forest had no current or anticipated need for API, there would be no value to it in obtaining a second source for API. The January 2022 Opinion rejected that argument. In the first instance, "the fact that Forest had sufficient API from Janssen could be entirely consistent with the opposite conclusion from the one offered by Direct Purchaser Plaintiffs—i.e., that Forest was in great need of another supplier." Dkt. No. 354 at 39. It was entirely plausible that Forest, as part of its "rational and competitive business strategy," *Twombly*, 550 U.S. at 554, would not want to be dependent upon a single supplier for what Plaintiffs themselves allege to be "at least [a] $37.5 million" contract, Dkt. No. 427 ¶ 163, and would want to develop a second source of supply to ensure competition.

[10] Plaintiffs refer to the Janssen agreement in the Complaints and rely on its effect. The Court may consider it on a motion to dismiss. *See* Dkt. No. 354 at 40 n.11.

Plaintiffs' new arguments do not address the deficiencies the Court identified in the Prior Complaints. Plaintiffs again allege that "Forest was able to obtain sufficient amounts of nebivolol API without a supply agreement with Hetero, and did not need this supply agreement," *id.* ¶ 164, and that "[t]here is no evidence Forest needed a back-up supply for nebivolol API," *id.* ¶ 168. They allege that they have found no publicly available information on Bystolic API supply issues and that the Form 10-K for the fiscal year ending in March 2012 stated that Forest "had not experienced any significant shortages in supplies of active pharmaceutical ingredients or other raw materials." *Id*. (citation omitted).[11] But Plaintiffs previously alleged on information and belief that Forest was not currently in need of API, *see* Dkt. No. 250 ¶ 154; the Court did not reject that allegation as conclusory. It assumed its truth but held it to be insufficient. The fact that Forest's needs were being satisfied by another source was "insufficient to raise a plausible inference that . . . the [] supply agreement with Hetero is unjustified." Dkt. No. 354 at 39. Plaintiffs' allegation that the 2012 Form 10-K does not say anything about Forest's needs just substantiates their information and belief. There is an obvious benefit for a manufacturer to not be reliant on a single source of supply even if that single source in the past has been able to satisfy its supply demands. Unless Forest was able to develop an alternative source, it would always be at the mercy of its sole source of supply.

Moreover, the statement from the 2012 Form 10-K that Plaintiffs cite only indicates that Forest had not experienced shortages *to date*. It provides no basis for inferring that Forest would

[11] The Court may consider the 2012 10-K form because Plaintiffs reference the form in their Complaints, relying on its statements and alleged omissions. *See*, *e.g.*, Dkt. No. 427 ¶¶ 167, 168, 179, 183. It was thus incorporated by reference. *See Chapman v. Mueller Water Prod., Inc.*, 466 F. Supp. 3d 382, 388 n.1 (S.D.N.Y. 2020); *cf. Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 383 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 35 (2d Cir. 2021) (laying out factors regarding when courts may consider documents incorporated by reference or take judicial notice and declining to consider 10-K form when it was not relied upon in plaintiff's complaint).

find no legitimate value, on a *forward-looking basis*, in a second source for additional Bystolic API. Forest's 2012 10-K Form, in fact, specifically identified the possibility of API shortages in its discussion of "Risk Factors." Forest identified the following risk in the same Form 10-K:

> *Many of Our Principal Products and Active Pharmaceutical Ingredients are Only Available From a Single Manufacturing Source.*
>
> Many of the proprietary active ingredients in our principal products are available to us only pursuant to contractual supply arrangements with our collaboration partners. . . . Difficulties or delays in the product supply chain, both within and outside of our control, or the inability to locate and qualify third party alternative sources, if necessary, in a timely manner, 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.

2012 Form 10-K, Forest Laboratories, Inc., at 24 (May 25, 2012), https://sec.report/Document/0000038074-12-000020/. The Form 10-K thus supports, rather than detracts from, the pro-competitive rationale of the supply agreement with Hetero.

Plaintiffs now also allege that no publicly available information reveals that Forest engaged in a bid selection process for the nebivolol API. Dkt. No. 427 ¶ 172. They further assert, in an entirely circular manner in their opposition brief, "[t]hat competitive bidding processes are typical in the industry is inherent in Plaintiffs' allegation that there is no public evidence Forest engaged in such a process." Dkt. No. 409 at 22. But those allegations are meaningless. The allegation that Forest did not state that it engaged in a bid-selection process is not evidence that it did not engage in such a process absent an additional allegation that such a disclosure would be required. The "absence of evidence is not evidence of absence." *See*, *e.g.*, *In re Rail Freight Fuel Surcharge Antitrust Litig.-MDL No. 1869*, 725 F.3d 244, 254 (D.C. Cir. 2013) ("The plaintiffs are right that the defendants' critique does not disprove the damages model's claim of classwide overcharges as a matter of logical necessity; absence of evidence is not evidence of absence."); *Saccenti v. Target Corp.*, 2021 WL 2716644, at *2 (E.D.N.Y. July 1,

2021) (noting, in summary judgment context, "the absence of evidence is not evidence of absence").

Further, Plaintiffs' assertion that it can be inferred that competitive bidding is typical because there is no evidence that Forest engaged in such a process is nonsensical. The more plausible inference is that with a product as specialized as API, there would be no need or opportunity for competitive bidding. Companies can engage in a business transaction that is mutually beneficial, pro-competitive, and based on "valid business judgment"—such as diversification of supply—without the agreement being the product of competitive bidding. *Brown v. W. Mass. Theatres, Inc.*, 288 F.2d 302, 304 (1st Cir. 1961) (noting that a departure from competitive bidding "does not in itself constitute or prove a violation, and cannot be helpful to the plaintiff unless he can rationally relate it to other conduct by the alleged conspirators"); *see also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 694–95 (1978) ("The Sherman Act does not require competitive bidding; it prohibits unreasonable restraints on competition."); *Orthopedic Studio, Inc. v. Health Ins. Plan of Greater New York, Inc.*, 1996 WL 84503, at *4 (E.D.N.Y. Feb. 9, 1996) (describing the "Sherman Act [a]s 'neither a lowest-responsible-bidder statute nor a panacea for all business affronts which seem to fit nowhere else'" (quoting *Scranton Construction Co. v. Litton Indus. Leasing Corp.*, 494 F.2d 778, 782 (5th Cir. 1974))).[12]

More important, the plain terms of the Janssen supply agreement and the Final Term Sheet refute any notion that the price Forest would have to pay to Hetero would be excessive, or that the agreement constitutes an impermissible means to funnel money to Hetero not for

[12] Plaintiffs also allege that the Final Term Sheet does not identify any cost savings to Forest or the price that Forest paid or expected to pay to Janssen for API. Dkt. No. 427 ¶ 169. But Plaintiffs have not alleged that cost savings, or identification of the price in a competitor's supply agreement, would normally be identified in such a Final Term Sheet.

product, but for Hetero to not compete. 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. That provision states that after January 1, 2016—a time period encompassed with the term of Final Term Sheet with Hetero—if Forest provides evidence of an offer for API supply "at a price that is at least fifteen percent (15%) lower" than the Janssen Price, then Janssen would have to elect to meet that price or else Forest would have the ability to terminate the Janssen supply agreement. Dkt. No. 270-3 § 4.3. Triggering the provision requires that Forest "notify [Janssen] of such Competitive Offer and provide [Janssen] with the Third Party communication documenting such offer." *Id*. The Final Term Sheet requires Forest to "use good faith efforts to amend its current supply agreement with Janssen . . . to permit Forest to meet the Purchase Minimum." Dkt. No. 270-2 at ECF p. 8. Moreover, the Final Term Sheet had its own meet-or-release provision with substantially similar language and terms, including a fifteen percent price threshold that would take effect after the first 24 months of the agreement.[13] *Id*. at ECF pp. 3–4.

The effect of these provisions in the two agreements is that Hetero's price would have to be competitive with Janssen's. Forest was not obligated to satisfy the Purchase Minimum from Hetero unless it was relieved of its obligation to purchase all of its requirements from Janssen, and Forest would not be relieved of its obligations to Janssen unless Hetero's offer was at least 15% cheaper than Janssen's price. 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

[13] The meet-or-release provision in the Final Term Sheet provided that "If Hetero does not elect to meet the price in such Competitive Offer, then the Purchase Minimum shall be reduced to 20% of Forest's commercial requirements . . . ." Dkt. No. 270-2 at ECF p. 4. If Hetero did not keep its price competitive, at least 60% of its minimum supply contract would be up for grabs.

in order for the Final Term Sheet to take effect. And on the assumption that the price was below the Janssen price (the only reasonable inference to be drawn on the facts alleged here), the Final Term Sheet—if converted into an enforceable agreement—would have a further pro-competitive effect. If Hetero sought to increase the prices it was charging Forest, then Forest would be able to leverage supply prices from Janssen to negotiate Hetero down. And if thereafter Janssen sought to increase its prices to Forest beyond what Forest was paying Hetero, Forest could use Hetero to negotiate Janssen down. The effect of those meet-and-release provisions is to "ensur[e] competitive pricing in a fluid market by assuring purchasers that a supplier will meet its competitors' rates." *Gen. Elec. Corp. v. BASF Corp.*, 2008 WL 4185870, at *2 (S.D.N.Y. Sept. 4, 2008). In short, there is no basis from the terms of the agreements to infer that the Final Term Sheet is anything other than legitimate.

Plaintiffs also infer that this was a "rush job" intended to convey a reverse payment, rather than a *bona fide* transaction. Dkt. No. 427 ¶ 170. Here, Plaintiffs repackage old facts: that the Final Term Sheet was shorter than the "typically lengthy and detailed" API agreement, was signed before Forest had obtained consent from Janssen to modify its supply agreement, and itself stated that it did not contain the "terms and conditions typical for manufacturing and supply agreements." *Id*. The parties also never entered into a final agreement after the Final Term Sheet. The Court addressed these allegations in the January 2022 Opinion and Plaintiffs plead nothing new to change its conclusion. The Court concluded that the "unfinalized nature of the final term sheet" "created obligations on Forest (as well as on Hetero) and that those obligations had value." Dkt. No. 354 at 41–42. The length of the Final Term Sheet is equally consistent with the conclusion that it was a preliminary agreement for subsequent negotiations. The mere fact that the Final Term Sheet was a preliminary agreement of the Type II variety, which

obligated the parties to negotiate the issues in good faith in an attempt to reach the ultimate contractual objective, *see Tchrs. Ins. & Annuity Ass'n of Am. v. Trib. Co.*, 670 F. Supp. 491, 498 (S.D.N.Y. 1987), is insufficient to raise a reasonable inference that the agreement itself was not a *bona fide* transaction.

Plaintiffs also point out prior non-API related transactions between Janssen and Forest and the timing of the Final Term Sheet to infer that it was not needed. They allege that Janssen had originally developed nebivolol in the 1990s and out-licensed the rights to Mylan in 2001, which then subsequently sublicensed those rights to Forest in 2006, Dkt. No. 427 ¶ 166; that Forest and Janssen in 2010 had entered in an agreement by which Janssen obtained the right to commercialize Bystolic and another product in Canada, *id*. ¶ 167; and that Forest purchased patents from Janssen, *id*. But that says nothing about Forest's competitive rationale for seeking supply from another supplier of nebivolol API, an entirely distinct product. The timing of the agreement—that it occurred seven months prior—again, "could be entirely consistent with the opposite conclusion from the one offered by Direct Purchaser Plaintiffs—i.e., that Forest was in great need of another supplier." Dkt. No. 354 at 39. Finally, Plaintiffs allege that Hetero "had never manufactured or sold the API product at issue." Dkt. No. 427 ¶ 171. But that is the point. It is precisely because Hetero had not manufactured the API in question before—because Forest was dependent on a sole supplier—that the Final Term Sheet would have value to Forest.

For these reasons, Plaintiffs have failed to state a claim with respect to the Hetero agreements.

2. Torrent

Forest executed a Settlement Agreement and License Agreement with Torrent that obligated Forest to pay up to $1 million to Torrent for Torrent's expended litigation fees and costs and Forest's saved legal fees and provided Torrent a license to sell generic Bystolic three

months before the patent expired. Dkt. No. 270-12. Forest also executed a Patent Assignment Agreement pursuant to which Torrent agreed to sell Forest ten patents covering compositions and/or manufacturing processes used in the development and manufacture of a prospective non-Bystolic nebivolol drug product for $17 million. Dkt. No. 427 ¶ 176; Dkt. No. 270-13.[14] The agreement thus contemplates payments from Forest in exchange for patents that may eventually be utilized in a new nebivolol drug product.

In the January 2022 Opinion, the Court rejected Plaintiffs' argument that the Patent Assignment Agreement did not convey value to Forest and was a disguised payment to refrain from competition. Plaintiffs had argued that Forest did not need the patents, and thus would not have valued them, because it was already manufacturing Bystolic and its period of exclusivity under the patent would come to an end by December 17, 2021. Dkt. No. 250 ¶ 158. The Court reasoned that "it does not plausibly follow that, because Forest had been able to manufacture and sell Bystolic, the Torrent patents had little or no value to Forest; there is a missing link between the first statement and the conclusion of no value." Dkt No. 354 at 45. The Court identified what was missing from the Prior Complaint. There were no facts pleaded:

> independently estimating the value of the patents; explaining why this patent assignment agreement did not comport with industry standards; showing that there had not been any previous dealings or discussions between Forest and Torrent on

[14] The Patent Assignment Agreement, under its definition of "Covered Nebivolol Product," for which Forest negotiated the assignment of the patents, explicitly delineates that "any nebivolol product that has been produced and marketed by Forest on or before the Effective Date shall not be deemed a Covered Nebivolol Product." Dkt. No. 270-13 § 1.4. The agreement defines "Covered Nebivolol Product" as "any 'Finished Nebivolol Drug Product' (that is, any drug product that contains nebivolol hydrochloride as an active ingredient in a final dosage form ready to be administered to a patient) sold and marketed in the United States (i) the composition of which, including any intermediate used or involved in the manufacturing process, is covered by at least one Valid Claim of the Assigned Patents or (ii) the manufacture of which, including the manufacture or use of all intermediates, is covered by at least one Valid Claim of the Assigned Patents." *Id*. Thus, the agreement, on its face, sought to allow Forest to utilize Torrent's patents to develop a new non-Bystolic nebivolol drug product.

> these patents; demonstrating that Forest had previously expressed no interest in these patents; or describing negotiations that were out of the ordinary for such patent assignment agreements.

Id. at 45–46. The Court stated that "[i]f the DPP Complaint contained factual allegations to support that the Torrent patents had little or no value to Forest, the DPP Complaint would then speak to the absence of bona fide fair consideration for the patents and the lack of Forest's need for these patents." *Id*. at 45.

In their Complaints, Plaintiffs do not offer any facts as to these issues. They do not plead facts regarding the value of the patents, that the Patent Assignment Agreement did not comport with industry standards, that there had been no prior dealings or discussions between Forest and Torrent, that Forest had previously expressed no interest in the patents, or that the discussions were out of the ordinary. Plaintiffs do allege that "patent licenses like those granted by Torrent are common side deals used by brand manufacturers to make reverse payments to their generic competitors," citing an Eastern District of Pennsylvania case. Dkt. No. 427 ¶ 180 (citing *King Drug Co. of Florence, v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 420–21 (E.D. Pa. 2015)). But that proposition is plainly overbroad. If accepted, it would render every patent assignment agreement entered into by a brand manufacturer providing a reverse payment presumptively suspect and anticompetitive, thereby undermining *Actavis*. In *King Drug Co.*, the plaintiffs had presented "expert opinions that [defendant] went outside industry norms and failed to conduct due diligence prior to licensing the Generic Defendants' IP" and defendant's chief patent counsel outright stated that they knew of "formulations of modafinil and [we]re not aware of any potential infringement problems" just months prior to the patent acquisition. *King Drug Co. of Florence,* 88 F. Supp. 3d at 420–21 (citation omitted). Plaintiffs do not allege similar facts here.

The new factual allegations in the Complaints add nothing that would make it plausible that the Patent Assignment Agreement was a disguised payment to Torrent for its agreement to

not launch a competing generic product. Plaintiffs allege that (1) it is unlikely that any newly issued Torrent patent could block Forest's sale of Bystolic because an earlier patent (the '580 patent) would be considered prior art;[15] (2) Forest had just "agreed to permit Hetero to launch generic Bystolic prior to the expiry of Forest's '040 Patent, rendering it implausible that Forest would seek additional patent protection and/or patents that would allow it to reformulate a product that was reaching the end of its life cycle"; (3) Forest had just "purchased from Janssen for $357 million what Forest characterized as 'all' U.S. patents and intellectual property for Bystolic, and it is 'unlikely' that Forest would have done so if it believed there were other relevant patents that might block its sale of Bystolic"; (4) Forest did not disclose in its SEC filings or any other public document that it was planning to develop a new form of Bystolic using the Torrent patents and did not put any public value on these patents; and (5) the milestone payment of $7 million was triggered by the issuance of any of the ten patents in the United States, so it is implausible that any of the patents in isolation had value. Dkt. No. 427 ¶ 179.

The alleged conduct "is consistent with and equally explicable by a pro-competitive justification," Dkt. No. 354 at 27 (citing *Twombly*, 550 U.S. at 559), that Forest wanted to purchase (and was able to purchase at a relatively low price) the intellectual property that could ensure that it would be able to successfully develop and sell a new non-Bystolic nebivolol product. That Forest had just purchased for $357 million the U.S. patents and intellectual

[15] This allegation sets up a strawman argument: the plain purpose of the agreement was not to preserve sales of Bystolic, as the Patent Assignment Agreement explicitly excluded Bystolic from its coverage. The contract allowed assignment for the purpose of Forest developing a new non-Bystolic nebivolol product. Even if the allegation did not rely on a strawman, the Court would decline to consider it because it is a legal conclusion that is not credited on motion to dismiss. *See Hamilton v. Westchester Cnty.*, 3 F.4th 86, 90 (2d Cir. 2021) ("We accept as true all factual allegations and draw from them all reasonable inferences; but we are not required to credit conclusory allegations or legal conclusions couched as factual allegations." (citation omitted)).

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.[16] Plaintiffs' allegation, which invokes Janssen's sale of patents for Bystolic, relies on a strawman that is implausible when assessed in light of the terms of the Torrent agreement.

Plaintiffs' argument that Forest had agreed to permit Hetero to launch generic Bystolic prior to the expiry of Forest's '040 patent, *see* Dkt. No. 427 ¶ 179, again relies on the mistaken assumption that the value of the patent agreement for Forest was in preserving its sales of Bystolic. Further, even if the patents were for Bystolic, the premise itself is flawed. Plaintiffs allege that it would be implausible for Forest to purchase additional patents for "a product that was reaching the end of its life cycle." *Id.* But according to Plaintiffs' pleadings, Forest and Torrent settled in 2012, approximately nine years before the "end of its life cycle," and Forest did not begin marketing Bystolic until 2008. *Id.* ¶ 178. Forest thus had only sold Bystolic—one of its "blockbuster" products, *id.* ¶ 161—for four years at the time of settlement, hardly a significant period in the product's life cycle. From Plaintiffs' own allegations, Bystolic

[16] Even if Forest's patent purchase from Torrent were for Bystolic, the previous patent purchase from Janssen would undermine any inference that Forest's purchase of the Torrent patents, after Forest had "s[old] nebivolol in the United States and other jurisdictions since 2008," lacked a pro-competitive rationale. Dkt. No. 427 ¶ 178. First, if (as Plaintiffs necessarily concede) there is nothing suspicious about Forest having paid $357 million to Janssen—which did not pose a risk of launching a competitive generic—there is no reason to infer that there is anything suspicious about Forest agreeing to pay $17 million to Torrent for patents for Bystolic. Forest had further disclosed in its 2012 Form 10-K that it "seeks to obtain, where possible patents and trademarks for [its] products in the United States and all countries of major marketing interest to Forest." 2012 Form 10-K, Forest Laboratories, Inc., at 20. That Forest had purchased all U.S. patents and intellectual property for Bystolic from Janssen for $357 million before purchasing the Torrent patents demonstrates the value Forest placed on Bystolic. Second, there is no allegation that Forest even knew about Torrent's patents at the time that they purchased Janssen's patents. Absent that allegation, it is entirely plausible that Forest valued and bought Janssen's patents without the knowledge that there were outstanding patents held by Torrent.

generated more than $1 billion a year in annual revenue. *Id.* ¶ 1. The more plausible reading of these facts is that Forest had a legitimate rationale for purchasing patents for one of its key products that had up to nine years remaining in its product lifespan.

Plaintiffs again allege that the $7 million payment in the Torrent agreement was triggered by the issuance of any of the ten assigned patents in the United States. *Id.* ¶ 178; Dkt. No. 250 ¶ 157. But Plaintiffs do not plead any metric to determine whether that payment was excessive, nor do they plead anything showing that the patents were valueless or not useful. Further, based on the terms of the agreement, Forest valued issuance of the patents *in the United States*. Dkt. No. 270-13 § 5.1. While six of the patents had already been granted in foreign jurisdictions, the application for the U.S. patent was still pending. *Id.* at Exhibit A. Forest placed a premium on a future grant of that patent, or an application derived from the other listed patents, in the United States, as such issuance would be essential to actualizing the value of the patents. Finally, the additional milestone payments under the agreement assigned value to the patents based on potential New Drug Applications, licensing, and infringement actions against third parties. *Id.* § 5.2; Dkt. No. 427 ¶ 177. Plaintiffs fail to construe the $7 million payment in the context of the agreement as a whole, which otherwise shows that patents issued in the United States were of value to Forest.

Plaintiffs also newly allege that Forest had not publicly disclosed that it was seeking to develop a new form of Bystolic, nor did Forest put any specific value on these patents in its 10-K for the fiscal year ending March 31, 2013. Dkt. No. 427 ¶ 179. Plaintiffs ask the Court to infer that because Forest did not disclose a value for the Torrent patents, an agreement to acquire those patents had little to no value. But, once again, Plaintiffs cite no facts for the proposition that Forest—a company that was acquired in 2014 for $25 billion, Dkt. No. 427 ¶ 8 n.5—would need

to disclose in its SEC public filings a $15 million acquisition of patents, none of which were even issued in the United States at the time. The more plausible inference is that the agreement was simply not material for SEC reporting purposes. Plaintiffs have not met their pleading burden on the Torrent agreements.

3. Alkem/Indchemie

Forest's agreements with Alkem/Indchemie included a Term Sheet pursuant to which Alkem/Indchemie agreed to supply, at minimum, 45% of Forest's requirements for tablets of two drugs, Bystolic and Byvalson (nebivolol and valsartan), for five years for sale and distribution by Forest in the United States and Canada. Dkt. No. 270-9. The agreement allows for two automatic renewal periods of one year each, provided that Alkem has capacity to supply the tablets and can do so at competitive prices defined as not more than 10% higher than generally available prices. Dkt. No. 427 ¶ 181; Dkt. No. 270-9 at ECF p. 3. Forest, in turn, agreed to pay Alkem/Indchemie at least $20 million. Dkt. No. 427 ¶ 181. In short, the agreement contemplates payments in exchange for the manufacture of final drug products.

The January 2022 Opinion concluded that Plaintiffs' pleading in the Prior Complaints that the payments exceeded the fair value of any products or services received, absent factual support, was "conclusory and a 'label' insufficient alone to state a claim." Dkt. No. 354 at 48. Plaintiffs also had not "allege[d] facts to support that, prior to signing the settlement agreements and Term Sheet with Alkem/Indchemie, Forest had expressed no interest in an agreement with those companies." *Id.* at 49. In short, "the plaintiff must allege that there is something about that agreement other than its timing and the fact that it results in the generic manufacturer honoring a patent that supports the inference that it is anticompetitive." *Id.*

The Complaint relies on provisions of the Term Sheet that the Court already found insufficient to support a plausible inference of anticompetitive conduct. Plaintiffs allege that

under the Term Sheet, Forest supplied Alkem/Indchemie with free API for the production of Bystolic and Byvalson tablets, and that Forest agreed to pay Alkem/Indchemie as much as a 10% premium over prices generally available from other supply sources for the final tablets. Dkt. No. 427 ¶ 181. But Plaintiffs mischaracterize the agreement they rely upon. The 10% figure represents the price increase that Alkem/Indchemie was permitted to charge after the expiration of the initial five-year term of the agreement, payable only if Alkem/Indchemie is "in material compliance with the Agreement . . . [,] has sufficient capacity to meet product demand and 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) with other comparable qualified sources of supply." Dkt. No. 270-9 at ECF p. 3. The "Commercial Price" of the tablets during the five-year term of the Term Sheet is defined as "no higher than the price" of $.02375/tablet for Bystolic tablets and $.0475/tablet for Byvalson tablets. *Id*. at ECF p. 6. In short, the provision provides protection—and thereby value—to Forest: it limits the amount by which Alkem/Indchemie can increase the price after the five years during which Forest will have become dependent on the former's products.

Plaintiffs also plead that the Term Sheet includes an additional term that Forest "shall reimburse [Alkem/Indchemie] for the costs and expenses incurred in connection with the Development Work." Dkt. No. 427 ¶ 184. Plaintiffs allege that this is a double payment for the same task, which is already compensated by the milestone payments. *Id*. The fact that there are distinct payments for milestones and expenses does not give rise to a reasonable inference that the agreement was one-sided, much less that it is not bona fide. The two payments are not connected in any manner—they constitute separately determined amounts. The milestone payments are fixed under the Term Sheet, while the expenses are determined according to a

"mutually agreed work-plan and budget." Dkt. No. 270-9 at ECF pp. 5–7. The expenses constitute reimbursements; the milestones constitute rewards for achievements. Alkem/Indchemie could receive reimbursements even if it achieved nothing; and Alkem/Indchemie could also receive rewards for its achievements, even if it accomplished them at little to no expense. Such payments are consistent with the notion that the milestones had independent and ascertainable value for Forest irrespective of the work undertaken to accomplish them.

Plaintiffs also allege that Forest was obligated under the agreement to make milestone payments even if developmental delays arose. Dkt. No. 427 ¶ 184. But Plaintiffs again omit key details of this term from their pleading. Forest's obligation to make payments arises only if there is a delay of greater than 90 days in the milestones "due to failure of Forest to perform its obligations or as a result of additional development or regulatory activities required to be performed by Forest." Dkt. No. 270-9 at ECF p. 6. In other words, Forest's obligation to pay was linked to Forest's failure to perform or Forest's need to undertake additional activities. No inference can be drawn from the fact that the agreement ensured payments from Forest when Forest created additional costs that the agreement was a disguised payment for the failure to compete.

The remainder of the Complaints' allegations regarding Alkem/Indchemie simply repackages information already before the Court and that the Court deemed insufficient. Plaintiffs allege that the Term Sheet was a "rush job" and that it was entered into without due diligence. Dkt. No. 427 ¶ 185. The Court previously rejected the claim that the timing of the Term Sheet makes it suspicious—that claim could be made with respect to every side agreement for products or services entered into simultaneously with the settlement of patent litigation. The

conclusion that the agreement was rushed appears to be based on nothing more than that it was embodied in a term sheet that was entered into prior to the completion of due diligence. But the fact that two companies that were settling litigation also agreed quickly to enter into a separate or related agreement for products and services—even if rushed—would not make that agreement suspicious. The opportune time for parties who were once adversaries to reach an agreement for products and services is when they are settling litigation. One would not necessarily expect them to agree to do business with one another when they were fighting on the litigation turf.

Further, Plaintiffs' assertion that it is "typical industry practice" for a pharmaceutical company to conduct due diligence on manufacturing facilities prior to entering into a binding agreement, *id*., does not render the Term Sheet suspect. The Term Sheet is just that: a term sheet. It reflects that due diligence would occur after its execution, including FDA Establishment Inspection Reports, scheduled visits by Forest personnel including a quality audit, and a customary quality agreement for the products. *Id*. The Term Sheet also contains numerous provisions designed to control product quality and oversee the manufacturing facilities. Under the Term Sheet, Alkem provided Forest with a copy of its last two FDA Establishment Inspection Reports and then would schedule visits by appropriate Forest personnel to conduct a quality audit. Forest and its agents also had a right, following notice to Alkem, to inspect the products, the holding facilities for such products, the equipment used in manufacturing the products, the laboratories used to test the products, and all records relating to the manufacture of the products. Dkt. No. 270-9 at ECF p. 7. Alkem was obligated to promptly notify Forest of any visit or inspection of the facility by regulatory authorities and to permit Forest to participate in any such visit or inspection. *Id*. Similarly, Forest owned and controlled all regulatory approvals and applications with respect to the product, and Alkem was obligated to "cooperate as necessary

in obtaining and maintaining such approvals." *Id*. Importantly, Alkem also agreed to a product warranty and indemnified Forest against losses arising out of third-party claims as a result of Alkem's breach of the agreement—including a lack of conformance with the product warranty—or gross negligence or willful misconduct. *Id*. at ECF p. 8.

Finally, Plaintiffs reallege—now based on their searches of the FDA website and public information—that Forest did not have supply shortages for the finished form of Bystolic and that Forest had not expressed any prior interest in retaining Alkem/Indchemie to manufacture Bystolic or Byvalson. Dkt. No. 427 ¶¶ 182–83. These statements were previously alleged on the basis of "information and belief" in the Prior Complaints. Dkt. No. 250 ¶ 161. The former allegation is insufficient, even if pleaded in a non-conclusory manner. The fact that Forest had not *previously* experienced supply shortages would not demonstrate that it was not at risk of supply shortages or—more pertinently—that the additional supply was not of value. As previously noted, Forest reported the risk of supply shortages, on a forward looking basis, in its March 2012 10-K Form. It noted that it had only a single manufacturing source for Bystolic in particular:

> *Our manufacturing facilities in the Republic of Ireland are the exclusive qualified manufacturing facilities for finished dosage forms of our principal products, including Namenda, Bystolic and Savella.* Difficulties or delays in the product supply chain, both within and outside of our control, or the inability to locate and qualify third party alternative sources, if necessary, in a timely manner, 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.

2012 Form 10-K, Forest Laboratories, Inc., at 24 (emphasis added).

The latter allegation—that Forest had not previously expressed an interest in retaining Alkem/Indchemie—is still conclusory. Plaintiffs now reveal the information and belief upon which they previously made the allegation: the absence of any public report that Forest had previously expressed an interest. However, as also previously noted, the "absence of evidence is

not evidence of absence." *See supra* Section II.1 (citing *In re Rail Freight Fuel Surcharge Antitrust Litig.-MDL No. 1869*, 725 F.3d at 254; *Saccenti*, 2021 WL 2716644, at *2). That Forest had not disclosed, prior to reaching an agreement with Alkem/Indchemie, that it was interested in reaching an agreement is not a fact from which one can infer that it had no such interest. To the contrary, the far more likely inference is that prior to reaching an agreement, it neither believed it had an obligation to disclose in SEC filings the inchoate interest nor had an interest in disclosure.

4. Glenmark

Concurrently with its Settlement Agreement and License Agreement, Forest and Glenmark entered into a Collaboration and Option Agreement pursuant to which Forest and Glenmark would jointly develop mPGES-1 products for a period of at least 27 months absent earlier termination. Dkt. No. 427 ¶ 188; Dkt. No. 270-15. The Collaboration and Option Agreement thus contemplates a joint research venture between the two entities. More specifically, the Collaboration and Option Agreement provides Forest an opportunity to take advantage of Glenmark's expertise and know-how in the discovery of small molecule inhibitors of mPGES-1. It establishes a program by which Forest—and no one other than Forest—may determine research priorities with Glenmark and receive research products from Glenmark. It also grants Forest a right of first negotiation as to any commercialization rights to products from the program. In exchange, the agreement requires Forest to pay $15 million to Glenmark. Dkt. No. 270-15 ¶ 4.1. Of that $15 million, $9 million is owed up front: $6 million is in consideration for the option rights granted to Forest and as reimbursement for research and development expenses associated with the mPGES-1 program, *id*. ¶ 4.1(a), and $3 million is an advance payment for the research and development services to be performed by Glenmark during the first nine months under the agreement, *id*. The remaining $6 million is designated as

subsequent research fee disbursements: $2 million is due on the nine-month anniversary for the ensuing six month period for "research and development services" or when Glenmark files an investigational new drug application with a regulatory authority to commence human trials, and $4 million is due on the fifteen-month anniversary for the ensuing twelve-month period for the same, or when Forest receives the Phase I data summary report from the first single ascending dose Phase 1 Study. *Id.* ¶ 4.1(b).

The January 2022 Opinion held that Plaintiffs had "failed to offer any factual allegations for why the allegedly large reverse payment is unexplained or unjustified." Dkt. No. 354 at 50. The Complaints allege that "[b]ased on inferences from publicly available information and the allegations contained herein, the payments under the Collaboration and Option Agreement exceeded the fair value of anything that Forest received." Dkt. No. 427 ¶ 188.

The Complaints reallege the following facts: (1) Forest had not previously expressed interest in the development of mPGES-1 prior to executing the Settlement Agreement and Collaboration and Option Agreement, *id.* ¶ 189; (2) the milestone payments were due "regardless of whether the product was successful," *id.* ¶ 191(a); (3) Forest did not receive intellectual property rights or development and commercialization rights in any market, *id.* ¶ 191(b); and (4) the only "right" Forest had under the agreement was a "Right of First Negotiation" that was valued by the Parties at less than $6 million, *id.* ¶ 191(c). The Complaints also draw on additional terms from the Collaboration and Option Agreement that if Forest and Glenmark could not negotiate an agreement for a resulting product in 120 days, Glenmark could enter into a deal with a third party so long as the deal was not "materially more favorable to such Third Party than the terms and conditions last offered by Glenmark to Forest." *Id.* Furthermore, the Complaints highlight that there was no mechanism for Forest to verify that such a deal was not

"materially more favorable" to a third party. *Id.* ¶ 192. In other words, the Complaints do not add to the allegations that the Court already found to be deficient.

There is nothing other than conclusory statements alleging that the payments under the Collaboration and Option Agreement exceeded the fair value of what Forest received. On its face, the Collaboration and Option Agreement provided substantial value to Forest.[17] It gave Forest a seat at the table and an opportunity to learn from and exploit Glenmark's expertise and know-how on inhibitors. Dkt. No. 270-15 ¶¶ A, B, 2.1, 2.5. The agreement required Glenmark as well as Forest to "work together cooperatively and in good faith in conducting and pursuing the goals of the mPGES-1 Program." *Id.* ¶ 2.2. Forest gained the right to appoint half of the representatives to a Joint Development Committee, *id.* ¶ 3.2, which would meet quarterly to monitor and potentially alter the program, *id.* ¶¶ 2.3, 3.2, 3.3, 3.4, 3.5. Forest gained the right to view and comment on Glenmark's investigational new drug applications with any regulatory authority and Glenmark was required to consider those comments "in good faith." *Id.* ¶ 2.4. Glenmark was required to provide quarterly reports to Forest on the status of the program and undertake "reasonable effort[s]" if Forest required additional information to verify any report, *id.* ¶¶ 2.6, 2.7, 2.8(b); Glenmark was also required to consider in good faith the comments of Forest on publications reporting the results of pre-clinical and clinical trials, *id.* ¶ 6.2.

At the end of the program, after Forest fulfilled its payment obligations and Glenmark fulfilled certain studies obligations and provided Forest certain data, Forest was given a 30-to-45-day period during which it could provide notice of its desire to exercise its "Right of First

[17] That the mPEGS-1 collaboration was not publicly available speaks little to whether the collaboration was justified or not. For the reasons previously mentioned under the discussion of the other agreements, the absence of such evidence does not reasonably lead to an inference that there was no justification absent additional facts alleging what such an absence implies.

Negotiation." *Id.* ¶ 6.4(b)(2).[18] The notice triggered a period of 120 days during which Glenmark was prohibited from negotiating with anyone else for a commercialization agreement. Glenmark was obligated to "negotiate with Forest in good faith exclusively" for a commercialization agreement. *Id.* ¶ 6.4(b)(3). Moreover, if no agreement was reached during that 120-day period, Glenmark was prohibited from entering into a binding agreement with any other party during the following nine months if the "terms and conditions of a binding agreement entered into by Glenmark in connection with any transaction entered into" were "materially more favorable to such [t]hird [p]arty than the terms and conditions last offered by Glenmark to Forrest." *Id.* ¶ 6.4(b)(5).

Plaintiffs again argue that "Forest was not granted any intellectual property rights" in the product. Dkt. No. 427 ¶ 191(b). But that reflects a fundamental misunderstanding of the agreement. The Forest-Glenmark agreement was for commercialization. The intellectual property would not have had value if it could not be commercialized. And the agreement provided substantial value to Forest in connection with commercialization. For the entire period of the mPGES-1 program, Forest and Forest alone would have the right to work with Glenmark on the development of potential products and possess access to Glenmark's trade secrets. For the term of the agreement, Glenmark was barred from providing any confidential information

[18] Defendants argues that this "was more akin to a right of first refusal than a 'right to negotiate.'" Dkt. No. 395 at 31. But the arrangement, as alleged and as described by the Defendants, is more like a right of first offer, rather than a right of first refusal. *See In re Adelphia Commc'ns Corp.*, 368 B.R. 348, 353 (Bankr. S.D.N.Y. 2007) ("A right of first refusal entitles the holder to match any subsequent offers for the property before the third party offeror can complete its transaction."). Forest retains no such entitlement to match any subsequent offers—the key element of a "right" of first refusal. But even then, Forest had secured a provision with commercial value because the agreement incentivized Glenmark to make its best offer to Forest because otherwise it would risk losing the ability to commercialize the mPEGS-1 product for nine months or have to commercialize the product on worse terms.

regarding the program to any third party, or engage in any evaluation, negotiation, or transaction with any third-party regarding mPEGS-1 involving sale, assignment, granting license to, creation of any encumbrance upon, or otherwise disposing of anything from the program. Dkt. No. 270-15 ¶ 6.4(a)(1). Thus, not only would Forest be able to develop the product, but it alone would have knowledge about both its scientific promise and its regulatory prospects. And the agreement obligated Glenmark to "negotiate with Forest *in good faith* exclusively" for 120 days, *id*. ¶ 6.4(b)(3) (emphasis added), and then gave Forest a right after that to block Glenmark for the following nine months—if it did not agree with Forest—from engaging in a transaction with anyone else on more favorable terms, ensuring that Forest could exploit its head start. In effect, unless Glenmark reached an agreement with Forest on terms Forest found acceptable, Glenmark would have to wait 120 days before negotiating with someone else who would not have the knowledge and information Forest accumulated over the course of the program's development. Glenmark would only then be able to enter into an agreement with that third party over the following nine months if the terms were not more favorable to that third party than what Glenmark had last offered to Forest in good faith. And Glenmark would have to make the decision whether to enter an agreement with Forest before knowing that a third party would emerge. In short, on its face, the Collaboration and Option Agreement conferred substantial value to Forest.

While the technology would remain Glenmark's, Forest thus had a right to participate in and oversee its development, ensure that no other party was able to access the confidential information developed through the collaboration, and make a first offer that was accompanied by significant incentives for Glenmark to say "yes." The milestone payments were for the obligations that Glenmark undertook as the entity responsible for the mPEGS-1 program and for

its expertise in the "discovery of small molecule inhibitors of [mPGES-1]." Dkt. No. 270-15 ¶ A. The $6 million payment ensured that Forest was first in line for any products from the program.

The only real new allegation, not already before the Court the last time, is that the Glenmark agreement is unlike a separate 2004 collaboration agreement between Forest and Glenmark, in which Forest retained rights to develop, register, and commercialize an already identified inhibitor, GRC 3886, in the United States, payments were completed upon milestones, and Glenmark would earn a mid-teens royalty from the product and supply API for sale by Forest. Dkt. No. 427 ¶ 190. But neither the Complaints nor Plaintiffs' briefing identifies why that agreement is significant. There is no allegation that the 2004 collaboration agreement constitutes the only form in which two companies can agree to collaborate. Nor is there an allegation that the challenged Forest-Glenmark agreement departs from industry standards. There also is no allegation that the products are even remotely similar. In fact, the pleading states that the 2004 collaboration agreement was for an *already identified* inhibitor for phosphodiesterase-4, "GRC 3886", *id.*, while the Collaboration and Option Agreement entailed the development of potential inhibitors for mPEGS-1, *see* Dkt. No. 27-15 § 1.25. Indeed, the fact that Forest and Glenmark did business with one another in the past tends to undermine Plaintiffs' claim rather than support it.

5. Amerigen

Forest's July 2013 agreements with Amerigen included a "Binding Term Sheet Collaboration Agreement" under which Forest obtained royalties from eight Amerigen products, including five "Additional" generic products in exchange for a nonrefundable up-front payment of $5 million plus an additional $20 million in contingent milestone payments. Forest also had the option to commercialize up to eight Amerigen products in Latin America and South America,

which Amerigen had the right to supply to Forest for its manufacturing costs plus 30% and on other customary and reasonable terms. Dkt. No. 427 ¶ 195; Dkt. No. 270-19.

Plaintiffs previously argued that "prior to executing the Settlement Agreement and Collaboration Agreement, Forest had expressed no interest in Amerigen's products." Dkt. No. 250 ¶ 165. The Court dismissed Plaintiffs' claims because Plaintiffs offered only "conclusory allegations on information and belief that relate to whether there was bona fide fair consideration for the property or services and whether there was a history of demonstrated interest in or need for the property or services." Dkt. No. 354 at 52.

Plaintiffs largely reiterate allegations and arguments made in their Prior Complaints without curing any of their deficiencies. Plaintiffs allege, based on "[s]earches of publicly available information," that Forest did not have a preexisting business relationship with Amerigen and did not express interest in Amerigen's products prior to the Settlement Agreement and Collaboration Agreement. Dkt. No. 427 ¶ 197. Those allegations previously were made "[o]n information and belief." Dkt. No. 250 ¶ 165. Plaintiffs do not allege that publicly available information shows that Forest did *not* have a preexisting relationship with Amerigen or did *not* have an interest in its products. They instead allege that the publicly available information does not show that Forest did have a preexisting relationship with Amerigen and also does not show that Forest did have an interest in Amerigen's products. The absence of that information, however, is not a fact from which one can infer that Forest lacked any such interest. There is no allegation that Forest would have been required to disclose the identity of every company with which it had a relationship, or the name of every product as to which it had internally expressed an interest or would have wanted to invest in had the opportunity presented. Indeed, it is unlikely that any company would ever make such a disclosure. The only inference

that can be drawn from the fact that public disclosures do not reveal that Forest previously had an agreement with Amerigen for generic products is that Forest did not previously have such an agreement that was material. But even if one could infer that Forest had not previously purchased rights from Amerigen with respect to a generic product, that does not give rise to a plausible inference that the agreement Forest ultimately entered was anticompetitive. The more plausible inference is that the agreement was intended to accomplish exactly what on its face it did accomplish—the transfer to Forest from Amerigen of future royalties in exchange for an initial investment in product development.

Plaintiffs further allege that "Forest did not truly care about whether [Amerigen's] products fit within its corporate focus." Dkt. No. 427 ¶ 197. Plaintiffs allege that Amerigen had the unilateral ability to discontinue development of any of the eight products, provided that Amerigen offered Forest at least two alternate products of similar value as the discontinued products. *Id*. But that does not make the agreement pretextual. Plaintiffs omit key portions of the provision that show that it had value for Forest. Amerigen was only able to discontinue the product "[i]n the event that Amerigen believes [it] . . . is no longer technically or commercially viable." Dkt. No. 290-19 at ECF p. 9. Amerigen thereafter must provide Forest a written rationale describing in reasonable detail the circumstances that led to that conclusion. *Id*. Forest was then entitled to request a meeting with Amerigen to discuss the discontinuation and Amerigen was obligated to give reasonable consideration to Forest's comments. *Id*. at ECF pp. 9–10. If Amerigen still wished to pursue the discontinuation, it had to propose two alternative products that are of "similar value," "taking into account probability of technical success, time to commercial launch and commercial potential." *Id*. at ECF p. 10. The provision thus allowed

Forest to *maintain* its corporate focus and the value of the agreement by giving it the option to choose its follow-up products and by ensuring that those products were viable.

The further allegation that Forest brands itself as focusing on "branded" drug products, and that the five "Additional" products in the Collaboration Agreement were generic products does not "nudge[] [Plaintiffs'] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Plaintiffs do not allege any reason why a company that sells branded products would not want, as a means of diversifying its portfolio, to also offer generic products. Forest's 2012 Form 10-K states that the process of developing new pharmaceutical products is time-consuming, expensive, and risky:

> *Our Business Model Currently Depends on the Successful In-Licensing or Acquisition of New Product Opportunities.*
>
> In order to remain competitive, we must continue to develop and launch new pharmaceutical products. Our pipeline of new products is currently dependent on the licensing and acquisition of new product opportunities. To successfully accomplish these transactions, we commit substantial effort and expense to seeking out, evaluating and negotiating collaboration arrangements and acquisitions. The competition for attractive product opportunities may require us to devote substantial resources to an opportunity with no assurance that such efforts will result in a commercially successful product.
>
> . . .
>
> *If We Are Unable to Successfully Develop or Commercialize New Products, Our Operating Results May Suffer.*
>
> Our future results of operations will depend to a significant degree upon our ability to successfully develop and commercialize new products. New product development is subject to a great deal of uncertainty, risk and expense. Promising pharmaceutical candidates may fail at various stages of the research and development process, often after a great deal of financial and other resources have been invested in their exploration and development. Even where pharmaceutical development is successfully completed, a product may fail to reach the market or have limited commercial success because the safety and efficacy profile achieved during the course of development is not as favorable as originally anticipated or is viewed by the marketplace as less favorable in comparison to new and competing therapies which may become available during the lengthy period of drug development. In addition, decisions by regulatory authorities regarding labeling

> and other matters could adversely affect the availability or commercial potential of our products.

2012 Form 10-K, Forest Laboratories, Inc., at 22–23 (italics in original). In this context, it would be "rational and competitive business strategy," *Twombly*, 550 U.S. at 545, for a company such as Forest to not close itself off from investment in a generic when the opportunity presents itself. The fact that Forest did so does not make the resulting agreement presumptively anticompetitive.

Finally, Plaintiffs allege that Forest did not finalize the agreements until one year later and several weeks after the FTC issued a Civil Investigative Demand ("CID") to Forest. Plaintiffs infer that this indicates that the "final agreement was driven by a desire to avoid antitrust liability." Dkt. No. 427 ¶ 198. The timing of the finalized agreement alone, however, does not raise a reasonable inference that the agreement was unjustified, particularly when the preliminary agreement—the Term Sheet—was entered into before the CID. The timing of the final agreement after the CID is equally consistent with the inference that Forest and Amerigen were executing their obligations under the Term Sheet.

6. Watson

The final challenged set of agreements concerning Watson includes (1) a "Termination and Release Agreement" ("Termination Agreement") between Actavis and Moksha8 that terminated a series of agreements between Watson and Moksha8 entered into from 2010 to 2012 and released Watson from obligations arising from those agreements, in exchange for Watson paying $4 million to Moksha8, Dkt. No. 270-6; and (2) a "Letter Agreement" between Forest and Moksha8 stating that Moksha8 was in material breach of at least three "Loan and Security Agreement[s]" but nonetheless committing Forest to extend to Moksha8 approximately $7 million in additional "Term C" loans, Dkt. No. 270-5. The Termination Agreement also released Watson from obligations related to transactions contemplated by a prior October 2012

Agreement and Plan of Merger by and among Forest, M8 Holdings LLC, and Moksha8 Parent (the "Merger Agreement") or agreements contemplated by the Merger Agreement. Dkt. No. 427 ¶ 200; Dkt. No. 270-6.

Plaintiffs previously argued that "[t]he November 2013 agreements entered between Forest, Moksha8, and Watson disguised large payments from Forest to Watson." Dkt. No. 251 ¶ 221. The January 2022 Opinion considered the Settlement and License Agreements, Letter Agreement, and Termination Agreement together. The Court concluded that Plaintiffs "ha[d] not sufficiently pleaded the existence of a reverse payment" because the Prior Complaints "lack[ed] factual allegations regarding how that transfer of value, or 'payment,' to Moksha8 was then conveyed to Watson." Dkt. No. 354 at 55. Plaintiffs also had failed to plead how the "release of all claims against Watson was more valuable than any consideration Watson paid for the releases." *Id*. The January 2022 Opinion concluded that "the DPP Complaint could have included facts describing the releases, explaining why the releases were valuable to Watson, and providing context to estimate their relative value even if precise estimates are not alleged." *Id*. at 56.

Plaintiffs again allege that an anticompetitive payment for delay to Watson occurred "by facilitating Watson's termination of its commitments to Moksha8 and release by Moksha8," Dkt. No. 427 ¶ 201, but nothing in Plaintiffs' new pleadings addresses the defects previously identified by the Court. In fact, Plaintiffs outright admit that their Complaints fail to remedy the defects. They state that "Plaintiff cannot tell precisely how Forest used the transaction with Moksha8 to transfer this payment to Watson, but there is a clear inference that it did so." *Id*. ¶ 215.

According to Plaintiffs, there are two agreements at issue. Under the Termination Agreement, Moksha8 and Watson relieved each other of any rights, obligations or duties against one another arising from a series of prior agreements. Dkt. No. 270-6 § 5. Watson also paid $4 million to Moksha8 as a part of that Termination Agreement. *Id*. § 3. Under the Letter Agreement, Forest loaned $7 million to Moksha8 and Moksha8 provided releases to Forest. Dkt. No. 270-5 §§ 2, 5. But Plaintiffs do not plead facts from which a factfinder could infer that either sets of agreements is for other than fair value. Nor do Plaintiffs plead facts to infer that value conferred upon Moksha8 by Forest was transferred to Watson. The Letter Agreement on its face appears to be for fair value; there is nothing suspect about it. Forest provided $7 million in debt financing to Moksha8. There also is nothing suspect about the Termination Agreement. Moksha8 agreed to accept payment from Watson in exchange for releases and the termination of Watson's commitments to Moksha8. In addition, Watson also released Moksha8 from claims it might have. Plaintiffs again have not shown how the "release of all claims against Watson was more valuable than any consideration Watson paid for the releases." Dkt. No. 354 at 55.

Plaintiffs' pleadings on background events in 2012 running up to the Letter and Termination Agreements also do not remedy the defects in their prior pleadings. Those allegations are irrelevant to the question of how value was transferred from Moksha8 to Watson, and how much value was transferred, if any. They were also previously before this Court on the prior motions to dismiss.[19] Events that occurred in October 2012—more than a year before the

[19] For example, Plaintiffs reallege that Forest purchased Watson's minority interest in Moksha8 in October 2012 for $47 million, but now add that the price was $17 million more than what Watson had invested two years earlier; reallege that the October 2012 Agreement also provided Moksha8 with up to $125 million in financing; and newly allege that the October 2012 agreement granted Forest a right to acquire Moksha8 at a fixed price of $157 million. They further allege that Watson recorded a gain of $28.8 million on this transaction. Dkt. No. 427 ¶¶ 207–10.

execution of the alleged reverse payments at issue in November 2013—offer no insight into *how* the November 2013 Letter and Termination Agreements themselves transferred payments either through releases or termination. Plaintiffs needed to plead more facts about the November 2013 agreements, and they have failed to do so.

To the extent that Plaintiffs' Complaints allege that the transfer occurred by Forest releasing its claims against Moksha8's "Guarantors,"—suggesting, perhaps, that Watson is one of those Guarantors—Plaintiff has not alleged any factual matter supporting that theory. Plaintiffs plead that Forest had a claim for damages against Moksha8 "and its Guarantors" based on Moksha8's breaches of its covenants in its October 22, 2012, November 29, 2012, and November, 30, 2012 Loan and Security Agreements. Plaintiffs, however, do not identify who those Guarantors are. Dkt. No. 427 ¶ 212. No allegation is made that Watson was a Guarantor. No facts are alleged indicating that releasing claims against the Guarantors somehow benefitted Watson.

Plaintiffs also have not shown that Forest conveyed payments to Watson in excess of $15 million. Plaintiffs again repeat their allegation that the inclusion of the Letter and Termination Agreements in Forest's February 2014 merger disclosures as "related to" the settlement agreement indicates that they involve payments in excess of $15 million. *Id.* ¶ 218. The Court squarely rejected that argument in its January 2022 Opinion, stating that Plaintiffs "focus on only one of the three disjunctive criteria [for inclusion as related to the settlement agreement]," with the other criteria being (1) monitoring or reporting obligations or (2) unsatisfied material conditions precedent to settlement. Therefore, the Court concluded that Plaintiff had not sufficiently pleaded that the inclusion of the Letter and Termination Agreements could not be due to those other two innocuous criteria. Dkt. No. 354 at 57. Plaintiffs, this time, argue that the

Letter and Termination Agreements must have been related to the criteria related to payment in excess of $15 million by stating that there is no mention of the other two criteria in the Letter and Termination Agreements. But a payment in excess of $15 million is also not mentioned in the Letter and Termination Agreements. Dkt. No. 354 at 57. Nor would monitoring or reporting obligations necessarily have been in the agreements themselves. The inference that the agreements met the other criteria is equally as plausible as the inference that there was a payment in excess of $15 million.

Finally, Plaintiffs allege that because Watson settled last, they must have received a large payment and it must have been for other than value. But that allegation, based purely on timing, is clearly insufficient to satisfy *Actavis*. There is always a last one to settle; sometimes it is the only defendant to be sued. Were Plaintiffs' allegation sufficient, then there would always be an antitrust claim with respect to every settlement of patent litigation for a reverse payment. *Actavis* clearly precludes that result. In fact, this Court previously held that "[w]here there are multiple generic manufacturers, it does not follow that simply because a reverse-payment agreement with one Generic Defendant is anticompetitive, the brand manufacturer's agreements with every other Generic Defendant is anticompetitive." *Id*. at 34.[20] Plaintiffs have not, in any event, established that any of the prior agreements were anticompetitive.

III. Defendants' Remaining Arguments

For substantially similar reasons as those outlined in the January 2022 Opinion, the Court need not address the Defendants' additional arguments for dismissing the Complaints. *See id*. at 57–59. These include the motions to dismiss for a lack of personal jurisdiction, *see* Dkt. No. 386

[20] Forest's abrupt termination of its obligations to provide additional funding does not rebut the pleading deficiency that Plaintiffs have not sufficiently alleged that any value was transferred to Watson.

(TEVA Israel's Motion), Dkt. No. 388 (Non-Resident Defendants' Motion), whether the alleged reverse payment is "large," Dkt. No. 395; Dkt. No. 405 (Amicus Brief in support of Defendants' motion to dismiss), and whether Plaintiffs allege a plausible theory of causation, Dkt. No. 395.

IV. Motions Regarding End-Payor Plaintiffs' Complaint

The remaining claims in the EPP Complaint are dismissed. The parties do not dispute that if the federal antitrust claims are dismissed, then the EPP claims under state antitrust law, based on the same factual allegations, are dismissed as well. Dkt. No. 354 at 61; Dkt. No. 411 at 2 ("There is no dispute that the state antitrust laws under which EPPs bring their antitrust claims are consistently interpreted in parallel, if not identically, with the federal antitrust statutes."). Similarly, the consumer protection claims must be dismissed as well because "they rely on the existence of anticompetitive conduct, which the Court has found insufficiently pleaded." Dkt. No. 354 at 63. The Court thus not need address Defendants' other arguments for dismissing the EPP claims. The motion to dismiss the EPP Complaint is granted with prejudice.

CONCLUSION

For these reasons, the Court holds that Plaintiffs have failed to state a claim with respect to all of the Agreements.

Defendants' motion to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim is GRANTED with prejudice. Defendants' motion to dismiss the End-Payor Plaintiffs' Complaint for failure to state a claim is GRANTED with prejudice. Nonresident Defendants' motion to dismiss the End-Payor Plaintiffs' Complaint's non-New York, state law claims for lack of personal jurisdiction and Teva Israel's motion to dismiss for lack of personal jurisdiction are DENIED as moot. The motion of the New Civil Liberties Alliance and the International Center for Law and Economics for leave to file an amicus brief is GRANTED.

The Clerk of Court is respectfully directed to close Dkt. Nos. 386, 388, 393, 397, 403. For the reasons explained in an accompanying Order, this Opinion and Order will be filed temporarily under seal until the Court can review any redactions the parties propose. The Clerk of Court is respectfully directed to file this Opinion and Order under seal, viewable only to the Court and the parties to this action.

SO ORDERED.

Dated: February 21, 2023
New York, New York

LEWIS J. LIMAN
United States District Judge