IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY	:	**CIVIL ACTION**
	:	
v.	:	**NO. 21-3500**
	:	
TAKEDA PHARMACEUTICALS, U.S.A., INC., *et al.*	:	

ORDER-MEMORANDUM

AND NOW, this 30th day of March 2022, upon considering Defendant Takeda Pharmaceuticals' Motion to dismiss (ECF Doc. No. 168), Plaintiff's Response (ECF Doc. No. 176), and Defendant's Reply (ECF Doc. No. 181), Defendants Watson and Amneal's joint Motion to dismiss (ECF Doc. No. 169), Plaintiff's Response (ECF Doc. No. 176), and Defendants' Reply (ECF Doc. No. 179), and Defendant Par Pharmaceutical's Motion to dismiss (ECF Doc. No. 170), Plaintiff's Response (ECF Doc. No. 177), and Defendant's Reply (ECF Doc. No. 180), following extensive oral argument, and for reasons below, it is **ORDERED**:

1. Defendant Takeda's Motion (ECF Doc. No. 168) is **GRANTED** without prejudice as to the Plaintiff's claims of separate bilateral conspiracies (Counts II, III, IV) and **DENIED** as to the claims for an overarching conspiracy to restrain trade, monopolization, conspiracy to monopolize, and (Counts I, V, VI);

2. Defendants Watson and Amneal's Motion (ECF Doc. No. 169) is **GRANTED** without prejudice as to the claims for separate bilateral conspiracies with Takeda (Counts III, IV), and **DENIED** as to the single overarching conspiracy to restrain trade (Count I) and conspiracy to monopolize (Count VI);

3. Defendants Teva Ltd. and Teva Pharmaceuticals USA, Inc.'s request to join Defendants' Watson and Amneal's Motion to Dismiss (ECF Doc. No. 169-1 at 5 n. 1) is

GRANTED, and the separate bilateral conspiracy claim (Count III) is **DISMISSED** without prejudice against the Teva Defendants;

4. Defendant Par's Motion (ECF Doc. No. 170) is **GRANTED** without prejudice as to the claim for a separate bilateral conspiracy with Takeda (Count II) allowing Par to join the co-Defendants' arguments and **DENIED** as to the single overarching conspiracy to restrain trade (Count I) and conspiracy to monopolize (Count VI); and,

5. Defendants shall answer the remaining allegations and claims in the first amended class action Complaint no later than **April 13, 2022**.

Analysis[1]

Takeda obtained Food and Drug Administration approval for Colcrys – a tablet of colchicine – to treat Familial Mediterranean Fever and prevent gout in July 2009.[2] This approval caused the twenty-one existing sellers of colchicine treatments to exit the market leading to prices for colchicine to increase dramatically.[3] Generic drug manufacturers Par, Amneal, and Watson – in this order – filed Abbreviated New Drug Applications with the Food and Drug Administration seeking approval for their generic versions of Colcrys, certifying Takeda's patents covering Colcrys are either invalid or not infringed by their generics.[4] Takeda sued each

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[1] We write solely for the parties familiar with the facts largely detailed in our December 29, 2021 Memorandum explaining why we granted the Defendants' Motions to dismiss the Complaint. ECF Doc. No. 157. Plaintiff Value Drug Company accepted our invitation to amend, regrouped, and pleaded additional facts in the first amended class action Complaint now before us. We address the limited newly pleaded facts material to today's analysis. We accept the pleaded facts in the light most favorable for a plaintiff when reviewing a motion to dismiss. ECF Doc. No. 157 at 38 n. 62 (motion to dismiss standard).

[2] ECF Doc. No. 163 ¶¶ 35–37. Takeda had exclusivity based on approval of its New Drug Applications until July 29, 2016. *Id.* ¶ 35.

[3] *Id.* ¶ 36.

[4] *Id.* ¶¶ 63, 65, 67.

of the three Generics for patent infringement in the District of Delaware.[5] Judge Robinson coordinated the cases and set a joint bench trial for Takeda's lawsuits against the three Generics (Par, Watson, and Amneal) to begin in December 2015.[6] Takeda settled with the three Generics on the eve of trial, giving rise to Value Drug's antitrust claims now before us.[7]

Value Drug is a pharmaceutical wholesaler who purchases Colcrys and generic Colcrys for resale.[8] It claims Takeda conspired to order market entry and restrict output through, among other things, separate settlement agreements with each Generic.[9] It alleges these three settlement agreements are part of a larger antitrust conspiracy to order market entry and restrict output of Colcrys or, in the alternative, separate bilateral conspiracies between Takeda and each Generic to achieve the same result.[10] Value Drug alleges Takeda and the Generics conspired to restrict

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[5] *Id.* ¶¶ 64, 66, 68. Takeda's suit against each Generic triggered the thirty-month stay in the Hatch-Waxman Act for each of their ANDA applications during which time the FDA would not give final approval to the Generics. *Id.* ¶¶ 60, 62, 69.

[6] *Id.* ¶ 100.

[7] *Id.* ¶¶ 109–16.

[8] *Id.* ¶ 1.

[9] The settlements are comprised of multiple written agreements, including the settlement agreement and license agreements. *See, generally*, ECF Doc. No. 163 beginning at 85.

[10] Value Drug alleges this conduct violated Sections 1 and 2 of the Sherman Act. Section 1 of the Sherman Act provides "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Section 1 antitrust plaintiffs must establish three things: (1) "a contract, combination . . . or conspiracy"; (2) an unreasonable restraint on trade; and (3) antitrust injury. *In re Insur. Brokerage Antitrust Litig.*, 618 F.3d 300, 314–15, 315 n.9 (3d Cir. 2010); *see also Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010). "[T]he existence of an agreement is the hallmark of a Section 1 claim." *In re Insur.*, 618 F.3d at 315 (citing *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 117 (3d Cir. 1999) (further citation omitted)). "Instead of assigning [contract, combination . . . or conspiracy] a distinct meaning, courts have interpreted them collectively to require 'some form of concerted action' . . . in other words, a 'unity of purpose or a common design and understanding or a

output by ordering the market entry of generic Colcrys products to share the supracompetitive profits for an extended period of time. Takeda and the Generics allegedly did so by staggering the Generics' entry and conspiring to hold off the "third wave" of Generics consisting of generic drug manufacturers who had not yet filed ANDA applications from entering the market for as long as possible to prevent the incremental price collapse which occurs with each generic entrant.

Value Drug pleads circumstantial evidence of a plausible, single horizontal conspiracy among Takeda and the Generics.

We again must determine whether Value Drug pleads a single horizontal overarching conspiracy among Takeda, Par, Watson, and Amneal. We conclude it does so on a second try. Value Drug may plead the conspiracy with direct or circumstantial evidence or a combination of both.[11] Value Drug alleges the direct evidence[12] of the conspiracy includes the settlement

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meeting or minds' or 'a conscious commitment to a common scheme.'" *Id.* (citing *In re Baby Food*, 166 F.3d at 117 and *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004)) (further citations omitted) (internal quotation omitted). Section 2, conversely, has "sweeping language" making it unlawful to "monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2). "A Section 2 conspiracy claim has four elements: (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged." *Howard Hess Dental Lab'ys Inc.*, 602 F.3d at 253. But a litigant may bring a Section 2 claim for monopolization as well, requiring "'(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *Broadcom Corp.*, 501 F.3d at 307. (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). The second element of a monopolization claim requires "the willful acquisition or maintenance of monopoly power." *Id.* at 308. "As this element makes clear, the acquisition or possession of monopoly power must be accompanied by some anticompetitive conduct on the part of the possessor." *Id.* (citing *Verizon Commcn's Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004)).

[11] *In re Generic Pharms. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 438 (E.D. Pa. 2018) (quoting *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010)). To

agreements themselves and statements in other litigation.[13] We found the direct evidence arguments unavailing when we dismissed the Complaint three months ago. We find the same again today as to direct evidence for the reasons we described in our extensive Memorandum.[14]

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proceed beyond a motion to dismiss a conspiracy claim, we must find a plaintiff plead "enough factual matter (taken as true) to suggest that an agreement was made." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (discussing pleading standard for conspiracy in Sherman Act Section 1 claim); *see also In re Insur.*, 618 F.3d at 320 ("*Twombly's* importance to the case before us, however, goes beyond its formulation of the general pleading standard. *Twombly* is also an essential guide to the application of that standard in the antitrust context, for in *Twombly* the Supreme Court also had to determine whether a Sherman Act claim alleging horizontal conspiracy was adequately pled."). We apply the same pleading standards to a Section 1 and Section 2 conspiracy claim. *See W. Penn Allegheny Health Sys., Inc*, 627 F.3d at 99–100. If relying exclusively on direct evidence of conspiracy, "the complaint must plead 'enough fact to raise a reasonable expectation that discovery will reveal' this direct evidence" of illegality. *In re Insur.*, 618 F.3d at 324 (quoting *Twombly*, 550 U.S. at 556); *see also In re Processed Egg Prod. Antitrust Litig.*, 821 F. Supp. 2d 709, 717 (E.D. Pa. 2011) (quoting *In re Insur.*, 618 F.3d at 324) (further citations omitted)). "And if the plaintiff alternatively expects to rest on the circumstantial evidence of parallel behavior, the complaint's statement of facts must place the alleged behavior in 'a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.'" *In re Insur.*, 618 F.3d at 324 (quoting *Twombly*, 550 U.S. at 557). "[R]egardless of whether the plaintiff expects to prove the existence of a conspiracy directly or circumstantially, it must plead 'enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of illegal agreement.'" *Id.* (quoting *Twombly*, 550 U.S. at 556). We look at the conspiracy as a whole when assessing each Defendants' involvement, and "[i]n short, the issue is whether the pleading delineates to some sufficiently specific degree that a defendant purposefully joined and participated in the conspiracy." *In re Processed Egg Prod.*, 821 F.Supp.2d at 718–20; *see also In re Generic Pharms.*, 338 F. Supp. 3d at 438.

[12] "Allegations of direct evidence of an agreement, if sufficiently detailed, are independently adequate" to plead a conspiracy. *In re Insur.*, 618 F.3d at 323–24. Direct evidence is "evidence that is explicit and requires no inferences to establish the proposition or conclusion being arrested" such as "a document or conversation explicitly manifesting the existence of the agreement in question." *Id.* at 323–24 n.23; *see also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Nos. 06-1797, 06-1833, 06-2768, 2014 WL 2813312, at *6 (E.D. Pa. June 23, 2014) (citing *In re Insur.*, 618 F.3d at 324 n.23)).

[13] ECF Doc. No. 163 ¶¶ 206, 208–209, 224.

[14] ECF Doc. No. 157 at 15–19. Value Drug offers no argument as to why the settlement agreements are direct evidence of an overarching conspiracy despite pleading as much in the first amended class action Complaint. But Value Drug tells us it "addressed [our] concern" about the judicial admissions made by Takeda and Par in other litigation by pleading the object of the conspiracy "was to order the market for generic Colcrys" and Watson and Amneal stood to

While Value Drug still does not plead direct evidence, it now pleads enough facts of circumstantial evidence to plausibly allege an overarching conspiracy.[15]

Value Drug pleads consciously parallel conduct. Takeda settled its patent litigation with the three Generics on the eve of its bench trial before Judge Robinson. Judge Robinson canceled the trial for Takeda, Watson, and Amneal following a status conference and stayed the trial as to Par in light of Takeda and Par's settlement.[16] Takeda negotiated and executed the agreements with the Generics nearly simultaneously, and the agreements contain similar provisions with

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benefit from this ordering by ensuring limited competition for 135 days after their launch. ECF Doc. No. 176 at 18. It did not. The statements detailed in paragraph 224(a)–(d) of the first amended class action Complaint all require an inference there is an overarching agreement among Takeda and the Generics. None of the statements "explicitly manifest[]" the existence of the agreement in question. While the statements may be direct evidence of the parties' *motive* to conspire, they are not direct evidence of the actual agreement. Value Drug does not plead direct evidence of a single, horizontal conspiracy.

[15] A plaintiff may plead an anti-competitive conspiracy violating federal law through circumstantial evidence. *See, e.g. In re Ins.*, 618 F.3d at 321. But mere allegations of parallel conduct are not enough, nor are allegations of "conscious parallelism." *Id.* ("Parallel conduct is, of course, consistent with the existence of an agreement; in many cases where an agreement exists, parallel conduct—such as setting prices at the same level—is precisely the concerted action that is the conspiracy's object. But as the Supreme Court has long recognized, parallel conduct is 'just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market.'" (quoting *Twombly*, 550 U.S. at 554)). "In order 'to avoid deterring innocent conduct that reflects enhanced, rather than restrained, competition,' . . . and in order to enforce the Sherman Act's requirement of an agreement, the Supreme Court has required that 'a § 1 plaintiff's offer of conspiracy evidence must tend to rule out the possibility that the defendants were acting independently." *Id.* (further citations omitted). "Some courts have denominated these facts, the presence of which may indicate the existence of an actionable agreement, as 'plus factors'" and although not exhaustive, our Court of Appeals recognizes three such plus factors: (1) motive to enter the conspiracy; (2) evidence defendants acted contrary to their interests; and (3) evidence implying a traditional conspiracy. *Id.* (quoting *Flat Glass*, 385 F.3d at 360). "[P]lus factors are simply circumstances in which the inference of independent action is less likely than that of concerted action." *In re Generic Pharm.*, 338 F. Supp. 3d at 448 (further citation omitted) (alteration in original).

[16] ECF Doc. No. 163 ¶¶ 100, 110–125, 208(a).

Watson's agreement referring explicitly to Par's and Amneal's agreements.[17] Takeda told Judge Andrews in earlier litigation Par, Watson, and Amneal enjoyed "a better deal" than the later ANDA filers.[18] These pleaded facts allow us to plausibly infer Takeda treated Par, Watson, and Amneal as a group and they each knew of each other's settlements.

Value Drug also pleads a plausible motive for each conspirator. Value Drug pleads: with each generic drug's entrance to the market, the price the drug companies can charge per dose incrementally decreases;[19] Takeda faced "certain" defeat in the patent litigation with Par, Watson, and Amneal—a defeat which would cause an end to Takeda's monopoly on Colcrys;[20] by entering the conspiracy, Takeda ensured it would maintain control of the Colcrys market for a longer period of time, maintaining its high profits;[21] by entering the conspiracy, Par would face no other generic competition when it took over selling Takeda's authorized generic, which it otherwise would have competed with had it seen the patent litigation through and prevailed;[22] Par also extended its market exclusivity period as the only generic from 180 days to 837 days;[23] and in entering the conspiracy, Watson and Amneal obtained 135 days of limited competition

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[17] *Id.* ¶¶ 110–125, 138, 208(a); *see also* ECF Doc. No. 157 at 6–8 (detailing terms of settlement and license agreements now attached to first amended class action Complaint as exhibits).

[18] *Id.* ¶¶ 133–34, 168–69, 224(a).

[19] ECF Doc. No. 163 ¶¶ 53–55.

[20] *Id.* ¶¶ 38–41, 74, 80–81, 83–100, 102.

[21] *Id.* ¶ 129.

[22] *Id.* ¶¶ 103–104, 110–13, 130–33.

[23] *Id.* ¶¶ 59, 63, 150. The license agreement required Par to remit a substantial royalty to Takeda for the sale of its authorized generic. *Id.* ¶ 131. But Par remained the only generic on the market for 657 days longer than it otherwise would have been entitled to under the regulatory scheme.

with only Par in the market for generics, allowing the generic price to be maintained at least twenty percent higher than when more than three generics sell on the market with the brand.[24]

In seizing on language in our December 29, 2021 Memorandum finding no plausibly pleaded conspiracy because it makes no economic sense to conspire to cause a price collapse – which Value Drug then pleaded[25] – Watson and Amneal argue this conspiracy also makes no economic sense because no other generic drug company had filed an ANDA at the time Watson, Amneal, and Par would have prevailed in the patent litigation, thus no other generic could have entered the market for at least twenty-two months, giving Watson and Amneal a longer period of exclusivity immediately than what it allegedly conspired to receive five years in the future. Watson and Amneal's argument may have merit on summary judgment. Aside from requiring a

[24] *Id.* ¶¶ 114–16, 134, 151, 168–69, 206.

[25] We dismissed the Complaint without prejudice because the conspiracy as pleaded was implausible and belied an inference of concerted action. *Id.* at 20–25. Value Drug then pleaded Takeda and the Generics conspired to preserve a two-entrant market for as long as possible, with each Generic enjoying a defined period of exclusive sales. ECF Doc. No. 1 ¶¶ 58, 60 ("Par even explained the logic behind the output-restriction conspiracy: ['] [A market with] a single branded drug (Takeda's Colcrys) and a single generic version (Par's authorized generic) only functions if the market for Colcrys-equivalent colchicine is limited to those two products. [] Although a drug market can maintain price stability with a single generic version of a drug on the market, multiple entrants often produce a market-wide price collapse with mass renegotiation and cancellation of supply agreements. [] The distribution agreement between Takeda and Par recognizes this dynamic and provides powerful incentives to ensure that the parties preserve the two-entrant market' . . . The conduct among Takeda, Par, Watson, and Amneal only makes economic sense if there was an agreement among the four of them to restrain their respective generic and authorized-generic output and prevent the price collapse that Par so vividly described."). But we knew from the terms of the license agreements this would not occur – Watson and Amneal never stood to benefit from defined periods of exclusive sales. Rather, if and when Watson and Amneal entered the market, the very price collapse the conspirators conspired to avoid would occur. We found this admission belied a finding of concerted action. But now Value Drug pleads the theory it merely argued in opposing the Defendants' previous Motions to dismiss – namely, the conspirators wanted to stave off the "third wave" of ANDA filers for as long as possible to prevent an incremental price decrease which occurs when each additional generic enters the market, thereby reducing each sellers' market share and profits. Value Drug's amended Complaint no longer belies a finding of concerted action. Discovery will assist our analysis of this alleged circumstantial evidence.

factual inquiry inappropriate on a motion to dismiss, it ignores the pleaded fact by entering the conspiracy, Watson and Amneal also achieved more limited competition than they would have faced had they prevailed in the patent litigation and entered the market with Prasco, who at that time sold Takeda's authorized generic, and Par—putting four generics on the market instead of three. We cannot draw inferences in Takeda and the Generics' favor on a motion to dismiss. And we make no judgment on whether Value Drug will be able to prove the motive it pleads to withstand summary judgment. Our inquiry here is plausibility. At this stage we find Value Drug now pleads a plausible motive.

Value Drug also plausibly pleads Takeda and the Generics acted against their unilateral interests in agreeing to order the market entry. Value Drug alleges generic drug companies generally want to bring their generic product to market as soon as possible.[26] Value Drug pleads it did not make sense for Takeda to stop selling its authorized generic with Prasco, and in the face of a certain win, it did not make sense for Par, Watson, or Amneal to delay their entry into the market absent the conspiracy and the benefits it stood to gain by it.[27] Takeda argues we should dismiss the first amended class action Complaint because these settlements constituted actions in each Defendant's unilateral interest. But Value Drug need not disprove all possible reasons for the settlements to plausibly plead the actions constituted actions against their unilateral interest but for the conspiracy to withstand a motion to dismiss.[28] Whether Value Drug

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[26] ECD Doc. No. 163 ¶ 141 n.39.

[27] *Id.* ¶¶ 74, 80–81, 83–85, 86–89, 90–106, 141–44.

[28] *See supra* n.15; *see also* Areeda & Hovenkamp, Antitrust Law § 1405b (4th & 5th ed. 2021) (discussing the Supreme Court's summary judgment holding in *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986), and concluding "[t]he Court surely did not mean that the plaintiff must disprove all nonconspiratorial explanations for the defendants' conduct. Not only did it use the word "tend," but the context made clear that the Court was simply requiring

can prove its allegations to withstand summary judgment is not before us today. Value Drug plausibly pleads this "plus" factor.

Additional key pleaded facts nudge Value Drug over the line from possibility to plausibility in pleading an overarching conspiracy based on circumstantial evidence. First, each license agreement contained an acceleration clause.[29] As Judge Koh recently explained in finding a plausible overarching conspiracy similar in part to the one reviewed today, these "acceleration clauses"[30] function as a "cartel enforcement mechanism" by "threatening 'reversion to competitive behavior' – *i.e.* immediate entry by [the generic co-conspirators] – if certain market events were to occur."[31] Thus, these "'penalties' for 'firms exceeding their agreed upon shares'

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sufficient evidence to allow a reasonable fact finder to infer that the conspiratorial explanation is more likely than not.").

[29] Value Drug misreads our earlier holding granting Defendants' first motions to dismiss. Value Drug asserts it "respectfully disagrees with the Court's prior view . . . the Contingent Launch Provisions in the agreements do not constitute evidence of coordinated conduct." ECF Doc. No. 176 at 17. Value Drug points us to page eighteen of our Memorandum where we found the separate bilateral settlement agreements did not constitute **direct** evidence of a single overarching conspiracy. ECF Doc. No. 157 at 18. We did **not** hold the contingent launch provisions are not evidence of **coordinated conduct**. We held the settlement agreements, containing the contingent launch provisions, are not **direct** evidence of an overarching conspiracy because it would require an inference from the agreements to conclude this, which is classic circumstantial evidence. We did not consider this issue in our circumstantial evidence analysis because Value Drug pleaded an economically implausible conspiracy, which ended our analysis. Value Drug now pleads a plausible conspiracy, and we now consider whether the contingent launch provisions provide further evidence of coordinated conduct. We find it does.

[30] We note the parties call these provisions different things: contingent launch provisions, acceleration clauses, etc. But the provisions discussed – no matter the name – are the same. The provisions at issue here appear in Section 1.3 of Par's license agreement with Takeda (ECF Doc. No. 163 at 100–01); Section 1.2 of Watson's license agreement with Takeda (ECF Doc. No. 163 at 192–93); and Section 1.2 of Amneal's license agreement with Takeda (ECF Doc. No. 163 at 234–35); *see also* ECF Doc. No. 163 ¶¶ 121–25 (discussing terms of license agreements), 139–42 (discussing "contingent launch provisions" purpose).

[31] *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, --- F. Supp. 3d ---, No. 20-2966, 2021 WL 3612497, at *29 (N.D. Cal. Aug. 13, 2021) (internal and further citations omitted).

are cartel mechanisms that 'give firms a disincentive to steal sales from one another' . . . [i]n other words, the Generic Defendants are bound together through mutually assured competition, if not mutually assured destruction."[32] We agree with Judge Koh "the acceleration clauses are even more 'potent' evidence of a 'conspiracy to [restrain trade and monopolize]' at the motion to dismiss stage."[33] And the events which took place after the parties settled the infringement litigation show (at least at this pleading stage) these acceleration clauses did in fact dissuade the Generics from defecting from the conspiracy. As Value Drug pleads, Takeda lost summary judgment in the Mitigare litigation and did not appeal the ruling.[34] Mylan, a member of the "third wave" of ANDA filers, found (and later successfully argued), this denial of summary judgment triggered its launch date in its settlement agreement with Takeda which allowed it to launch upon a final court decision invalidating or finding the Colcrys patents uninfringed.[35] Par, despite its reasoned suggestion at oral argument it had incentive to get out from under the substantial royalty it paid to Takeda under its license agreement,[36] fought *against* Mylan's entry into the market, which would have allowed it to launch its own generic[37] and no longer pay the royalty.[38] Takeda and the Generics argue about theories derived from their view of the pleaded facts. We cannot join them in this analysis.

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[32] *Id.* at *30.

[33] *Id.*

[34] ECF Doc. No. 163 ¶¶ 85, 160.

[35] *Id.* ¶¶ 127, 160, 163.

[36] ECF Doc. No. 196, Oral Argument Transcript (Tr.), Mar. 10, 2022, at 77:15–80:2.

[37] ECF Doc. No. 163 at 100, Section 1.3(c).

[38] *Id.* ¶¶ 161–62, 166–67.

Considering these pleaded facts together and drawing all reasonable inferences in favor of Value Drug, we find Value Drug pleads a plausible single horizontal conspiracy among Takeda, Watson, Par, and Amneal by pleading consciously parallel conduct, a plausible motive for each conspirator, the conspirators acted against their unilateral interests, and additional pleaded facts supporting an inference of conspiracy, all of which together tend to rule out the possibility of independent action.

Value Drug does not plead plausible separate bilateral conspiracy theories to restrict output.

While we prefer to avoid opining in the negative, Value Drug's unique arguments on its bilateral conspiracy theory require we defer to what Value Drug argues this case is not. Value Drug concedes it does not plead a large and unjustified reverse payment. Value Drug argues because this is not a "pay-for-delay" scheme, it need not meet the Supreme Court's tests in *FTC v. Actavis* to state a claim.[39] Value Drug expressly repeatedly disclaimed it seeks to proceed under this theory of antitrust liability. And it tells us it does not seek to challenge the "acceleration clause" provisions *themselves* as violative of the Sherman Act.

So this is not an *Actavis* pay-for-delay scheme. Value Drug instead maintains Takeda engineered three separate output restriction conspiracies with each Generic as an individual co-conspirator with Takeda. Takeda and the Generics argue Value Drug is functionally arguing a pay-for-delay theory but calling it something else, and because it admittedly fails to plead a large and unjustified reverse payment, its bilateral conspiracy claims fail under *Actavis*. The parties agree there is no authority post-*Actavis* allowing Value Drug's output restriction conspiracy theory to go forward when challenging patent settlement agreements in the context of the Hatch-

[39] 570 U.S. 136 (2013).

Waxman Act. We also did not find authority for this theory. But the parties disagree about whether allowing this theory to go forward is breaking new ground or merely applying traditional antitrust principles to decide whether the three agreements are anticompetitive to the level of raising antitrust concerns.

We begin with two maxims: patent-related settlement agreements can sometimes violate antitrust laws, and in reviewing a case like this we must balance "the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act";[40] and, reduced output is an anticompetitive effect sufficient to plead an unreasonable restraint on a motion to dismiss.[41]

But both sides' arguments have some merit here. Value Drug's pleaded conspiracy is Par agreed to *delay* its market entry in exchange for 837 days of exclusivity, and Watson and Amneal agreed to *delay* entry in exchange for 135 days of limited competition, none of which could be enjoyed by the Generics but for the conspiracy. In other words, the Generics agreed to delay their entry in exchange for value – sharing large profits due to supracompetitive prices. But despite the apparent transfer of value here forming the alleged motivation to enter the conspiracy, Value Drug disclaims the "large and unjustified" reverse payment theory.[42] So Takeda and the Generics seize on Value Drug's strategy by arguing Value Drug can call its

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[40] *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 401 (3d Cir. 2015) (quoting *Actavis*, 570 U.S. at 147–48) (internal quotations omitted).

[41] *W. Penn Allegheny Health Sys., Inc.*, 627 F.3d at 100 ("[A] plaintiff may satisfy the unreasonable-restraint element by alleging that the conspiracy produced anticompetitive effects in the relevant markets . . . [a]nticompetitive effects include increased prices, **reduced output**, and reduced quality.") (emphasis added).

[42] We make no judgment on whether Value Drug could sustain a claim based on a large and unjustified reverse payment theory here because Value Drug told us it did not plead it and did not want to proceed under this theory.

theory whatever it wants, but the essence of the theory is "delayed" market entry **but** permitting entry before the patent expiration, which the Supreme Court taught in *Actavis* requires a large and unjustified reverse payment to raise antitrust concerns.[43] Otherwise, Takeda and the Generics argue, any patent settlement agreement, including those allowing entry before patent expiration, will be subject to antitrust scrutiny.

After some time considering this interesting issue, we realized we need not today decide it because Value Drug's bilateral conspiracy theory is implausible. The object of the conspiracy could not be achieved without all three Generics' active and knowing participation belying a theory Takeda conspired separately with each Generic. [44]

The very facts which make Value Drug's overarching conspiracy theory plausible make the separate bilateral theory implausible. Most importantly, and as shown in part by the

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[43] *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 359 (3d Cir. 2020), cert. denied sub nom., *AbbVie Inc. v. Fed. Trade Comm'n*, 141 S. Ct. 2838 (2021) ("As to AbbVie's settlement with Teva, the District Court erred in concluding it was procompetitive as a matter of law. Granted, the District Court was right that under *Actavis*, 'an agreement does not run afoul of the antitrust laws' if it simply allows a generic company to enter a market before patent expiration . . . And it was reasonable for the Court to think this exception reflects the Supreme Court's view that such agreements are so often procompetitive they should be legal per se. Still, the exception applies only if a patentee does not 'pay[ ] the challenger to stay out [before patent expiration],' and the District Court erred in concluding this condition was met here . . . The Court said AbbVie 'did not make any payment, reverse or otherwise, to ... Teva.' . . . Because the FTC plausibly alleged the TriCor deal was a reverse payment, the settlement may have been 'something more than just an agreed-upon early entry'—it may have been 'pay-for-delay.' . . . And pay-for-delay is anticompetitive even if the delay does not continue past patent expiration.") (internal citations omitted); *see also In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, No. 2895, 2022 WL 736250, at *10 (D. Del. Mar. 11, 2022) (Judge Stark finding the plaintiffs' market allocation theory "effectively a pay-for-delay theory and, hence, 'depends upon an allegation of an unlawful reverse payment' governed by the rule of reason test under *Actavis*. . . The Court sees no good reason to treat this part of Plaintiffs' market allocation theory as a standalone claim; all of the allegations (and, eventually, evidence) supporting this theory can be included as part of the reverse payment theory the Court has already held will proceed").

[44] In light of this finding, we do not analyze whether there is direct or circumstantial evidence of each bilateral conspiracy because the conspiracy as plead is implausible.

acceleration clauses in the license agreements, the success of the horizontal, temporal "market allocation" conspiracy required Par's, Watson's, and Amneal's participation and buy-in, lending support to Value Drug's overarching conspiracy claim. But the fact the conspiracy would not work absent all three Generic ANDA filers' participation belies the plausibility each Generic conspired *itself* with Takeda.

For example, there is nothing in Par's agreements with Takeda which gives it an extended exclusivity period. The terms of the agreements with Takeda give Par a date to start selling Takeda's authorized generic and a date which it can sell its own ANDA product. Par's benefit of 837 days of exclusivity, rather than 180 days provided by the regulatory scheme, derives from Watson and Amneal agreeing to stay off the market until October 15, 2020. How then could Takeda and Par alone conspire to order the market and receive this economic benefit? Takeda and Par could not *alone* achieve the preservation of a two-entrant market for an extended period; they needed Watson and Amneal. The same is true for Watson's and Amneal's benefit, which depended in part on Par agreeing to continue selling Takeda's authorized generic when Watson and Amneal began selling their generics rather than Par launching its own generic. Ordering the market as alleged here required all four conspirators' active and knowing participation to derive the benefit to the conspirators. In other words, all three Generics had to agree here to achieve the object of the conspiracy as pleaded – "restrict[] . . . output of generic Colcrys in order to keep prices from falling" and enjoy supracompetitive profits.[45] This reality alone necessitates a finding all three Generics participated in *one* conspiracy with Takeda, rather than three separate bilateral conspiracies. We dismiss as implausible Value Drug's claims

[45] ECF Doc. No. 163 ¶¶ 221, 235, 247.

alleging Takeda conspired with each Par, Watson, and Amneal individually to order the market and restrict output.

Value Drug plausibly pleads antitrust injury.

Par moves to dismiss arguing Value Drug fails to plead antitrust injury.[46] Par does not challenge Value Drug's allegation of an "injury of the type antitrust laws were intended to prevent"; rather, Par challenges the injury "*flows* from that which makes [the] defendants' acts unlawful" because it did not have final approval to launch its generic drug in 2016 when Takeda's exclusivity expired.[47] Value Drug sufficiently pleads antitrust injury at this stage.[48]

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[46] Establishing antitrust injury is required, but not sufficient, to establish antitrust standing. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164, 164 n.54 (3d Cir. 2017). Par only challenges Value Drug's failure to plead antitrust injury, no other element of antitrust standing. We only review whether Value Drug adequately pleads antitrust injury.

[47] We note the other Defendants seek to join Par's motion which only substantively addresses the facts plead against Par. But neither Watson nor Amneal offers substantive argument as to why the claims against it should be dismissed based on antitrust injury aside from seeking to join Par's motion. ECF Doc. No. 169-1 at 5. This conclusory joinder does not meet their burden on a motion to dismiss.

[48] Antitrust injury is an "injury of the type the antitrust laws were intended to prevent *and* that flows from that which makes [the] defendants' acts unlawful." *In re Wellbutrin XLs*, 868 F.3d at 164 (quoting *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 233 (3d Cir. 2013) (emphasis added)). The anticompetitive conduct must be a material or proximate cause of the antitrust injury, but a plaintiff need not allege the anticompetitive conduct *solely* caused the injury "[n]or must a plaintiff 'completely discredit in its initial pleadings all possible intervening causes' of its injury." *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114, n.9 (1969) ("It is enough that the illegality is shown to be a material cause of the injury. . ."; *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-2445, 2017 WL 4910673, at *11 (E.D. Pa. Oct. 30, 2017). And while "a regulatory or legislative bar can break the chain of causation in an antitrust case", when a defendant has engaged in conduct to delay regulatory approval in some manner, antitrust injury is met. *In re Wellbutrin XL*, 868 F.3d at 165; *In re Suboxone*, 2017 WL 4910673, at *13; *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 398–99 (D.N.J. 2018). But generally whether a plaintiff suffered antitrust injury involves "complex questions of fact" ill-suited for resolution on a motion to dismiss. *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997); *see also In re Suboxone*, 2017 WL 4910673, at *14; *In re Generic Pharms. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 457 (E.D. Pa. 2018) ("To the extent that the Court has been asked to analyze the issue of antitrust standing on a motion to dismiss, the Court's analysis falls under the

Value Drug alleges the intricacies of the Hatch-Waxman Act's statutory scheme under which generic drug manufacturers obtain tentative and final approval to market their generics.[49] Value Drug alleges: when a generic drug manufacturer files its ANDA with a paragraph IV certification, as all the Generics did here, the brand can sue for patent infringement, triggering a thirty-month stay during which time the Food and Drug Administration can issue tentative approval but will not issue final approval;[50] the Food and Drug Administration will also not issue final approval if the brand drug has exclusivity, like Takeda had here until July 2016;[51] receiving tentative approval from the Food and Drug Administration means the "ANDA meets the technical and substantive requirements for final approval, but final approval cannot be granted because of the existence of, for example, a patent which a Paragraph III certification has been filed (meaning that the ANDA filers intend to wait unti[l] patent expiry before marketing its own product) or that has been judicially determined to be infringed by the ANDA filer, or regulatory exclusivity such as a 30-month stay";[52] the Food and Drug Administration does not automatically grant final approval once the regulatory bar is lifted;[53] the applicant with tentative approval *must* request final approval and "generally [the generic] submits an amendment to its

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Twombly/Iqbal plausibility standard governing motions to dismiss under Rule 12(b)(6)."). While antitrust injury involves complex questions of fact, we address the *sufficiency* of the plaintiff's pleading at the outset to determine whether antitrust injury is plausibly pleaded. *McCullough v. Zimmer, Inc.*, 382 F. App'x 225, 230 (3d Cir. 2010).

[49] ECF Doc. No. 163 ¶¶ 42–48.

[50] *Id.* ¶¶ 44–45.

[51] *Id.* ¶¶ 35, 46, 70, 181 n. 47.

[52] *Id.* ¶ 46.

[53] *Id.* ¶ 47.

ANDA explicitly requesting final approval to market its drug product";[54] and, "[a] request for final approval with no new data, information, or other changes to the ANDA generally requires 90 days for FDA assessment."[55]

Par and Watson obtained tentative approval in February 2015 and October 2015, respectfully – suggesting they met the "technical and substantive requirements" for final approval before Takeda's exclusivity ended.[56] Amneal received final approval in September 2016.[57] Neither Par nor Watson obtained final approval, like Amneal, anywhere near July 2016 when Takeda's exclusivity ended.[58] Value Drug pleads the earliest day Par could have applied for final approval and pleads Par did not request final approval on this date, albeit in a footnote.[59] And while this is helpful and satisfies the pleading standard as to Par, based on Value Drug's pleading, we can also reasonably infer Watson and Par did not request final approval at the earliest date they could have, and thus, they both delayed obtaining final approval. In other words, Par and Watson needed to take an affirmative step to obtain final approval after meeting the substantive and technical requirements to obtain it. We can reasonably infer from the pleaded

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[54] *Id.*

[55] *Id.* ¶ 48.

[56] *Id.* ¶¶ 70–71.

[57] *Id.* ¶ 72.

[58] Watson obtained final approval on July 31, 2019. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=204461#37139 (last visited Mar. 20, 2022). Par obtained final approval on August 12, 2021. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=203976#19172 (last visited Mar. 20, 2022).

[59] ECF Doc. No. 163 ¶¶ 70, 181 n. 47. Nothing in this Order should be construed to approve the pleading of facts in footnotes arguably contrary to Federal Rule 8.

facts they did not take this action at the earliest date possible given Value Drug's pleading of the estimated time it takes for the Food and Drug Administration to grant final approval and the fact neither received it until years after Takeda's exclusivity ended. It is reasonable to infer Par and Watson's own conduct caused the delay in final approval; thus, the chain of causation is not broken here. Value Drug plausibly alleges antitrust injury at the motion to dismiss stage.[60]

KEARNEY, J.

[60] *Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d at 398 ("Nonetheless, Takeda maintains that Zydus has failed to obtain regulatory or tentative FDA approval, and therefore, its alleged injuries actually stem from the Hatch-Waxman's statutory framework as opposed to the instant dispute. However, Takeda's arguments require a factually intensive analysis which this Court cannot perform, because this case is still in its procedural infancy."), 398–99 (collecting cases); *Otsuka Pharm. Co. v. Apotex Corp.*, 143 F. Supp. 3d 188, 193 (D.N.J. 2015) (finding plaintiff a competitor for antitrust standing purposes absent FDA approval because it intended "to manufacture and directly distribute/sell its proposed generic"); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 4910673, at *13 (The movant "fails to establish that the FDA action was a purely independent cause fully accountable for the alleged antitrust injury, rather than a merely intervening cause"); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 159–60 (E.D.N.Y. 2018); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No. 06-52, 2010 WL 1485328, at *7 (D. Del. Apr. 13, 2010);; *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 356 (D.N.J. 2009); *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *12–13 (D.N.J. Aug. 28, 2009).