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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS DIRECT PURCHASER ANTITRUST LITIGATION

No. 15-CV-3278 (RA)

OPINION AND ORDER

RONNIE ABRAMS, United States District Judge:

This case concerns whether several pharmaceutical companies are liable to the direct purchasers of brand and generic versions of two diabetes drugs, called ACTOS and *ACTOplus* met ("Direct-Purchaser Plaintiffs" or "DPPs"), for unlawfully inflating those drugs' prices in violation of federal antitrust laws. Specifically, DPPs assert monopolization and restraint of trade claims, pursuant to Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, against the innovators of ACTOS and *ACTOplus* met ("ACTO*plus*"), Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"). DPPs also assert claims under those provisions against the following companies marketing generic versions of ACTOS and *ACTOplus*: Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (together, "Mylan"); Actavis PLC and Watson Laboratories, Inc. (together, "Actavis"); Ranbaxy, Inc., Ranbaxy Laboratories, Ltd., and Ranbaxy Pharmaceuticals, Inc., (collectively, "Ranbaxy"); and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together, "Teva"). Before the Court are Defendants' motions to dismiss. For the following reasons, the motions are granted, except for Takeda's motion to dismiss the individual monopolization claim against it.

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BACKGROUND

Familiarity with the related case brought by indirect purchasers of ACTOS ("End-Payor Plaintiffs" or "EPPs"), which arises from most of the alleged conduct in this case, is presumed. In that case, both this Court and the Second Circuit have recounted the relevant regulatory and factual background in detail. *See In re Actos End-Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2019 WL 4805843, at *1-4 (S.D.N.Y. Sept. 30, 2019) ("*End Payor III*"); *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 93-97 (2d Cir. 2017) ("*End Payor II*"); *In re Actos End-Payor Antitrust Litig.*, No. 13-CV-9244 RA, 2015 WL 5610752, at *1-16 (S.D.N.Y. Sept. 22, 2015) ("*End Payor I*"). For the purposes of this Opinion, the Court restates only the background information necessary to resolving the instant motions.

I. Regulatory Background

The issues in this case largely revolve around the proper interpretation of a provision of the Hatch-Waxman Act (the "Act"), which controls how and when manufacturers of brand name drugs, and their generic counterparts, can lawfully enter the market. Normally, inventors obtain patents for their brand-name drugs. Patents that protect a drug may include claims directed to: (1) a single active ingredient of the drug, that is, a chemical compound, referred to in the Act's supporting regulations as a "drug substance" claim; (2) multiple active ingredients of the drug, that is, a chemical composition, referred to as a "drug product" claim; or (3) a method of using the drug, referred to as a "method-of-use" claim.

Inventors must get FDA approval to lawfully sell their drugs. To do so, they must file New Drug Applications (NDAs) with the FDA. When filing an NDA that seeks approval to market a particular brand drug, inventors are required to submit information concerning related patents. The

scope of one of the Act's provisions governing when (and what) information about such patents must be submitted with an NDA is at the heart of this case.

For each patent that is submitted as part of an NDA, the applicant must describe the patent as a drug substance, drug product, or method-of-use patent, depending on the nature of the claims included in each patent. *See End Payor II*, 848 F.3d at 98–99. When an NDA is approved, the patent description and other information submitted with the application is listed in conjunction with the NDA number and the drug name, among other things, in the FDA's so-called "Orange Book."

If generic-drug manufacturers wish to sell a generic version of a brand-name drug they must first file with the FDA an Abbreviated New Drug Application (ANDA). Any ANDA must contain "an appropriate certification" for each patent listed in connection with the NDA in the Orange Book. If the generic-drug manufacturer intends to market a drug before a listed patent has expired, then it must tell the FDA that the generic will either not infringe the brand's patents, or that the brand's patents are invalid. Under the Act, there are two primary ways by which generics can do so.

First, generics can certify that the brand's patents are "invalid or will not be infringed by" their generic, which is referred to as a "Paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Because the Act provides that the filing of a Paragraph IV certification constitutes an act of infringement, *see* 35 U.S.C. § 271(e)(2)(A), the brand may then sue the generic accordingly. To incentivize generic manufacturers to challenge invalid patents (and therefore run the risk of being sued by patent holders), the first generic to file a Paragraph IV certification may receive a 180-day period during which it has the exclusive right to market a generic version of the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Where there are multiple first-filers

(i.e., more than one generic submits a Paragraph IV certification on the same day), they share the 180-day exclusivity period. The exclusivity period can be very lucrative for these first-filer generics who successfully challenge patents. The FDA will not grant final approval of later generics' ANDAs (preventing those generics from launching) until after the 180-day exclusivity of the first-filers has run. The exclusivity period does not, however, preclude market entry by so-called "authorized generics," which are sold by the brand or through a licensed third-party generic drug manufacturer.

Second, if the generic is seeking to market only a new *method of using* a drug, it can "carve out" any patented methods of use in its proposed label for the drug by submitting a so-called Section viii statement. *See id.* § 355(j)(2)(A)(viii) ("Section viii statement"). Successful applications that carve out patented methods of use under Section viii allow generics to enter the market even during the 180-day exclusivity period held by the first successful Paragraph IV filer. *End Payor II*, 848 F.3d at 95. A brand company may nonetheless sue a generic company with an FDA-approved Section viii statement, by asserting an induced infringement claim, pursuant to 35 U.S.C. § 271(b). In other words, although the FDA's approval of a Section viii statement suggests that the generic will be marketing the drug for a non-patented method-of-use, a brand company may assert a claim that the generic still intends to induce infringement of a *patented* method-of-use.

If a patent submitted with an NDA includes *both* drug substance or drug product claims, in addition to method-of-use claims, the generic can either file an ANDA with Paragraph IV certifications as to all claims, or they can file one with a so-called "split certification." In a split-certification, the generic submits a Paragraph IV certification as to the drug substance and/or drug

product claims, and Section viii statements as to the claims covering the patented methods of use that it intends to carve out from its label.

When a brand sues a generic for infringement of a patent listed in the Orange Book, the generic may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of § 355] on the ground that the patent does not claim either—(aa) the drug for which the [brand's NDA] was approved; or (bb) an approved method of using the drug." *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 409 (2012). If successful, the generic may obtain a judgment directing the brand to remove the patent information blocking the FDA's approval of the generic drug product.

II. Factual Background

Starting in the 1980s, Takeda obtained several patents related to its diabetes medicines. The first of those patents, U.S. Patent. No. 4,687,777 (the "'777 patent"), claimed the compound "pioglitazone," the active ingredient in Takeda's brand-name drug ACTOS. Takeda later obtained two other patents—U.S. Patent Nos. 5,965,584 (the "'584 patent") and 6,329,404 (the "'404 patent")—which claimed compositions of pioglitazone combined with other drugs. More specifically, the '584 patent claims compositions of pioglitizaone with metformin, and methods of using those combinations; the '404 patent claims compositions of pioglitazone with an insulin secretion enhancer, and methods of using those compositions.

A. The ACTOS Applications and Litigation

To obtain FDA approval to sell ACTOS, Takeda filed a New Drug Application (NDA) in January 1999, in which it submitted information regarding the '777 patent and described it as a drug substance patent. The FDA approved the NDA in July 1999 and listed the '777 patent in the

Orange Book. Later in 1999, and then in 2002, Takeda submitted information with respect to the '584 and '404 patents, respectively, in connection with the ACTOS NDA, describing those two patents (hereinafter, "the Patents") as both drug product patents and method-of-use patents—and improperly so, in DPPs' view. Those patents were also subsequently listed in the Orange Book for the ACTOS NDA, along with eight other patents that Takeda reported contained only method-of-use claims covering ACTOS. At the time, however, the Orange Book was only capable of displaying one description per patent listed. Thus, although the Patents were described to the FDA as both drug product patents and method-of-use patents, the Orange Book listings displayed only that they were described as method-of-use patents until starting in 2003.

1. The First-Filer ACTOS ANDAs

On July 15, 2003, Defendants Mylan, Actavis, and Ranbaxy (the "first generics") filed ANDAs seeking FDA approval to market generic ACTOS. These first generics challenged the validity and potential for infringement of the Patents with respect to their proposed ACTOS generics by submitting Paragraph IV certifications as to the Patents' drug product claims. They also submitted Section viii statements with respect to the Patents' method-of-use claims, seeking to market ACTOS for uses not covered by those patents.

In response, Takeda sued the first generics in this district, asserting that their ACTOS ANDAs induced infringement of the claims in the '777 patent and the Patents. Takeda's lawsuits against the first generics were consolidated. Judge Cote, who presided over these cases, decided to try Mylan's challenge to the '777 patent first. After a bench trial in 2006, Judge Cote ruled that the '777 patent was not invalid and that Mylan's ACTOS ANDA would infringe the patent.

2. Teva's ACTOS ANDA

In July 2004, Teva filed an ANDA seeking approval to market generic ACTOS. Teva's ANDA included only Section viii statements with respect to the Patents' method-of-use claims; unlike that of the other generics, Teva's ANDA did not contain any certifications with respect to the Patents' drug product claims. Despite that the ANDA did not do so, Teva still received tentative approval from the FDA for its ACTOS ANDA in February 2006. Three years later, Takeda sued Teva, asserting that its ACTOS ANDA would induce infringement of the '777 patent and the Patents. The lawsuit was consolidated with Takeda's lawsuits against the first generics.

3. The Sandoz Citizen Petition and Takeda's 2010 Statements

Soon after Takeda sued Teva, the FDA received a so-called citizen petition from non-party Sandoz Inc., essentially asking it to deny final approval of Teva's ANDA on the ground that it lacked a Paragraph IV certification as to the Patents' drug product claims. Critically, as a result of that petition, Takeda informed the FDA in January 2010 that the Patents had been properly described as both drug product and method-of-use patents for the ACTOS NDA. As a matter of practice, the FDA relies on such representations without independent evaluation. *See End Payor II*, 848 F.3d at 96–97. Based on Takeda's representations, the FDA granted the citizen petition on March 15, 2010. The FDA thus required that the ACTOS ANDAs, including Teva's—in addition to those of other non-party generics that filed ANDAs throughout this time (the "later-filers")—contain an appropriate Paragraph IV certification for the Patents explaining why the generic did not infringe those patents' drug product claims or that those claims were invalid. *See id.* (citing FDA Resp. to Sandoz Citizen Pet., No. FDA-2009-P-0411-0010 (Mar. 15, 2010) (Weiner Decl., Ex. A (Dkt. 260-1)). As explained in further detail below, the first generics settled their lawsuits with Takeda around this time.

B. The ACTO*plus* Applications

In August 2005, the FDA approved Takeda's NDA for ACTO*plus*, which contains a combination of the active ingredient in ACTOS, pioglitazone hydrochloride, with metformin hydrochloride. Takeda listed the '584 patent in the Orange Book for the ACTO*plus* NDA, as well as three other method-of-use patents.

In March 2008, Mylan submitted an ANDA seeking approval to market generic ACTO*plus*. Mylan made a Paragraph IV certification as to each patent listed for the ACTO*plus* NDA, and Takeda accordingly sued Mylan in August 2008. Mylan was the only first-filer for ACTO*plus* and was entitled to an 180-day exclusivity period.

By early 2009, Teva submitted an ANDA for generic ACTO*plus* which, unlike its ACTOS ANDA, included a Paragraph IV certification. In response, Takeda sued Teva, asserting that its *ACTOplus* ANDA (as well as its earlier-filed ACTOS ANDA, as noted) would induce infringement of the Patents' claims.

C. The Settlement Agreements

Takeda ultimately settled its lawsuits with the first generics in March 2010 and with Teva in December of that year. DPPs assert that each of these settlements constituted unreasonable restraints of trade and were the result of a conspiracy between Takeda and the other Defendants (hereinafter the "Generic Defendants") to unlawfully extend Takeda's monopoly over the ACTOS and ACTO*plus* drug markets.

1. First Generics' Settlement Agreements

On or about March 15, 2010, Takeda entered into settlement agreements with the first generics (Mylan, Ranbaxy, and Actavis) regarding the ACTOS litigation (and *ACTOplus* litigation with respect to Mylan). Pursuant to the agreements, the first generics were each granted a non-

exclusive license by Takeda to enter the market with a generic ACTOS product on August 17, 2012—that is, 20 months after the '777 drug substance patent expired, and almost four years prior to the expiration of the Patents. The agreements further provided that if any other generic ACTOS product entered the market on a date before August 17, 2012, the first generics could also enter the market on such a date (the "coordination clauses").

Mylan was also granted a non-exclusive license to enter the market with a generic version of ACTO*plus* on December 14, 2012, or August 17, 2012, if Takeda's sales of ACTO*plus* fell below a certain threshold. In addition, if any other generic ACTO*plus* product entered the market before the date specified for Mylan to enter, Mylan could also enter the market at that time.

Ranbaxy and Actavis' agreements further contained purported "side deals." Compl. ¶ 293. Ranbaxy's agreement provided it with a distribution right to enter the market with an authorized generic ACTOS under terms allegedly more favorable than fair market terms. Even though Ranbaxy had not filed an ANDA seeking approval to market ACTO*plus*, Takeda also gave Ranbaxy a distribution right for ACTO*plus*. Likewise, Takeda also gave Actavis a distribution right for ACTO*plus*, even though Actavis too had not filed an ANDA seeking approval to market the drug.

None of the agreements prohibited Takeda from issuing additional licenses to generic manufacturers or from licensing an authorized generic to manufacture generic ACTOS on its behalf. Neither the FTC nor the Department of Justice objected to the settlements.

D. Teva's Counterclaim and Following Settlement

On March 30, 2010, shortly after the settlements with the first generics were announced, Teva filed a motion to amend its answer to add a de-listing counterclaim against Takeda pursuant to 21 U.S.C. § 355(j)(5)(C)(ii). The counterclaim sought to delete the description of the Patents

as drug product patents for the ACTOS NDA, on the grounds that Takeda's statements to the FDA that those descriptions were accurate were false. The court stayed the motion to add the counterclaim and adjourned the consolidated trial date following a telephone conference with the parties on April 14, 2010. By December 21, 2010, Teva and Takeda settled the lawsuit. Teva agreed to withdraw its challenges to Takeda's patents in connection with its ACTOS and ACTO*plus* ANDAs. In exchange, Takeda granted Teva licenses to launch authorized generic versions of ACTOS and ACTO*plus* during the first 180 days of generic marketing, and non-exclusive licenses for Teva to market its own generic versions of the drugs after the first 180 days of generic marketing. The agreement also included a coordination clause, providing that if any other generic ACTOS or ACTO*plus* products entered the market before the date specified for Teva, Teva could then enter the market on that date as well.

E. Allegations of Conspiracy

DPPs allege that the March 2010 settlement agreements were "in reality a single deal between all four companies," that constituted a conspiracy to restrain trade and perpetuate Takeda's monopoly in the ACTOS and ACTO*plus* drug markets, in violation of §§ 1 and 2 of the Sherman Act. Compl. ¶ 273. In support of this theory, they emphasize that the lawsuits that were settled were consolidated; the settlements were announced within days of each other; the entry dates for the ACTOS products were the same; while the terms of the agreements were confidential, each permitted Takeda to share them with other generics; and that none of the first generics would have agreed to the later entry dates for ACTOS and ACTO*plus* without knowing that their generic competitors were getting the same deal. Teva's December 2010 settlement allegedly reflects its decision to join the purported conspiracy.

III. Procedural Background and the Related *End-Payor* Litigation

On June 4, 2015, DPPs filed a Consolidated Class Action Complaint, asserting many of the claims currently before the Court.

On September 22, 2015, the Court issued its *End-Payor I* decision, dismissing the EPPs' complaint in its entirety with prejudice. *See End Payor I*, 2015 WL 5610752, *29. On November 12, 2015, the Court granted DPPs leave to amend the then-operative complaint in light of *End Payor I*. DPPs filed their Second Amended Complaint on January 8, 2016. On January 28, 2016, Takeda filed a motion to dismiss DPPs' § 2 claim against it (Dkt. 64); Teva and Actavis filed a joint motion to dismiss for lack of standing (Dkt. 58); and Defendants further filed a joint motion to dismiss DPPs' remaining § 1 claims and overarching conspiracy claims under §§ 1 and 2 (Dkt. 61). DPPs filed a consolidated opposition (Dkt. 75), to which Defendants replied (Dkts. 80–83).

On May 27, 2016, in light of the appeal of *End Payor I*, the Court stayed this case pending the Second Circuit's resolution of the appeal. After the Second Circuit issued its decision on February 8, 2017, *see End Payor II*, 848 F.3d 89, the Court granted DPPs' request for leave to amend the complaint again. *See End Payor*, No. 13-CV-9244 (RA), 2018 WL 540099, at *7 (S.D.N.Y. Feb. 12, 2018). DPPs filed their request, attaching the proposed Third Amended Complaint, on April 6, 2017. The request was granted and the operative complaint ("Complaint") was filed on November 16, 2017. Defendants subsequently filed supplemental memoranda of law in support of their pending motions to dismiss (Dkts. 98, 105), after which DPPs filed a consolidated opposition (Dkt. 105), and Defendants replied (Dkts. 107–108).

On September 30, 2019, the Court denied Takeda's motion to dismiss the monopolization claims against it in *End Payor III*.

LEGAL STANDARD

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). On a Rule 12(b)(6) motion, the question is "not whether [the plaintiff] will ultimately prevail," but "whether [its] complaint [is] sufficient to cross the federal court's threshold." *Skinner v. Switzer*, 562 U.S. 521, 529–30 (2011) (internal quotation marks omitted). In answering this question, the Court must "accept[ ] all factual allegations as true, but 'giv[e] no effect to legal conclusions couched as factual allegations.'" *Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017) (quoting *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010)).

DISCUSSION

I. Monopolization Claim Against Takeda (Count I)

DPPs' monopolization claim against Takeda, based on Takeda's allegedly improper Orange Book listings, is essentially identical to that asserted by the EPPs most recently in *End Payor III*, 2019 WL 4805843, at *6. The same goes for Takeda's motion to dismiss that claim in these two related actions. For the reasons provided in *End Payor III*, DPPs have plausibly alleged that Takeda's January 2010 statements to the FDA, in response to the Sandoz Citizen Petition, constituted anti-competitive conduct. *See End Payor III*, 2019 WL 4805843, at *6–18. As was the case with the EPPs, DPPs here have further plausibly alleged that this anti-competitive conduct

caused antitrust injury by delaying both Teva's entry, and the entry of the other generics, into the ACTOS drug market. *See id.* at *18–20. DPPs' monopolization claim, to the extent based on Takeda's statements to the FDA, will thus proceed.

II. Remaining Claims Premised on the Settlement Agreements (Counts II–VIII)

Unlike EPPs in *End Payor I*, DPPs here do not predicate their antitrust claims arising from the settlement agreements on the reverse payment theory endorsed by *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). The underlying considerations articulated in *Actavis*, however, are still relevant to this Court's analysis of DPPs' alternative theory.

A. *Actavis* and *End Payor I*

In *Actavis*, the FTC filed suit against a brand manufacturer and generic competitors for entering into "reverse payment" settlement agreements after the brand sued the generics for patent infringement. 570 U.S. at 145. Pursuant to those settlements, the generics agreed not to bring their generic products to market for several years and further agreed to promote the brand drug to doctors in exchange for a "reverse payment"—that is, a payment flowing from the patentee brand to the alleged generic infringer—of millions of dollars. *Id.* The FTC claimed that these suits violated antitrust law because they caused the generics to abandon their patent challenges and refrain from launching their own low-cost generic drugs in exchange for a share of the brand's monopoly profits. The Eleventh Circuit affirmed the district court's dismissal of the suit, holding that a reverse payment agreement was generally "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 146. It found that to be the case for the settlements at issue.

In reversing the Eleventh Circuit, the Supreme Court rejected the notion that the anti-competitive effects of a settlement agreement that are within the scope of the patent's exclusionary

potential are immune from antitrust liability. It explained that, to determine whether a patent had been used in a manner that violates the antitrust law, the Court in its prior precedent had considered "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 149. Applying those considerations to reverse payment patent settlements, the Court concluded that "a reverse payment, where large and unjustified," is subject to antitrust scrutiny under the rule of reason, pursuant to which an antitrust defendant may show the lawfulness of the reverse payment if legitimate justifications are present.[1] *Id.* at 158.

At the same time, the Supreme Court clarified that patent suits may be settled by other lawful means. As relevant here, it specifically noted that parties may settle "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.*

In *End Payor I*, this Court held that the settlements between Takeda and the Generic Defendants did not contain large and unjustified reverse payments under *Actavis*. It explained that "[a]t their core, the settlements at issue simply granted the Generic Defendants a compromise date of entry[,] the very type of settlement sanctioned by the *Actavis* Court." 2015 WL 5610752, at *14. The Court rejected the notion that the coordination clauses had the anticompetitive effect of deterring other generics from challenging Takeda's patents. It further held that even if it "were to credit Plaintiffs' speculation as to how other generics would have acted if not for the [coordination]

[1] This conclusion was based on the following considerations: "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments." *Id.* at 158.

clauses it remain[ed] unpersuaded that this kind of settlement term is unlawful under *Actavis*." *Id.* at *16.

The Court also concluded that the ACTO*plus* licenses given to Ranbaxy and Actavis did not amount to unlawful reverse payments for the additional reason that those generics were not permitted to enter the market until after Mylan's 180-day exclusivity expired. As such, they were not given "any competitive advantage over other generic ACTO*plus* competitors." *Id.* at *17. Finally, Teva's agreement did not amount to a reverse payment because, among other reasons, the royalty payments were made from Teva to Takeda (i.e., not in reverse), and licensing Teva to enter the ACTOS and ACTO*plus* markets as an authorized generic—during the first 180 days of generic marketing—indisputably increased generic competition during those periods. EPPs did not appeal the dismissal of their claims based on the settlement agreements.

B. DPPs' Non-Reverse-Payment Theory of Antitrust Liability

Faced with the *End Payor I* decision concluding that the settlement agreements in this case do not contain reverse payments under *Actavis*, DPPs now allege that the settlement agreements constitute unreasonable restraints of trade, or a monopolistic scheme, under a novel, non-reverse payment theory.[2] Although this new theory is alleged in exhaustive detail, it is unsupported by current law. Because DPPs ultimately cannot establish that the settlement agreements are subject to antitrust scrutiny under their non-reverse-payment theory, their claims based on the individual settlement agreements fail, as do their overarching conspiracy claims.

[2] In their briefing, DPPs expressly abandon the theory that the settlement agreements restrained trade by including unlawful reverse payments under *Actavis*. *See* DPPs' Mem. Opp. at 2–3 (noting that Defendants' arguments regarding reverse-payment allegations are "largely directed to a different lawsuit entirely," namely, the *End-Payor* case, and that such arguments are "irrelevancies"). At oral argument, the Court confirmed with DPPs that they were no longer pursuing their restraint of trade claims under a reverse-payment theory. *See* Oct. 23, 2018 Hr'g Tr. at 77:21–78:5.

As previously explained, in March 2010, Takeda settled its Paragraph IV litigation against the first generics arising from their ACTOS ANDAs (and ACTO*plus* ANDA with respect to Mylan). Under those agreements, Takeda granted the first generics a non-exclusive license to enter the market with a generic ACTOS product on August 17, 2012—or, pursuant to the coordination clauses, even earlier if any other generic ACTOS product entered the market before then. That date was 20 months after the '777 ACTOS drug substance patent expired, and almost four years prior to the expiration of the Patents. Teva's December 2010 settlement with Takeda similarly granted Teva an authorized generic distributorship for ACTOS with the same coordination clause. And the Generic Defendants were also granted non-exclusive licenses to enter the ACTO*plus* market several years before the '584 patent covering that product expired.

DPPs argue that these agreements are subject to antitrust scrutiny because they "exploited Takeda's 'beyond-the-patent-scope' acts"—namely, "the underserved 180-day exclusivity." DPPs' Suppl. Opp. at 18. According to DPPs, Defendants knew at the time they settled with Takeda that the 180-day exclusivity had been obtained through Takeda's allegedly fraudulent statements to the FDA. They claim that the agreements violated antitrust law as a result, because the exclusivity period created an oligopoly—outside the scope of the Patents—in which Defendants charged supra-competitive prices for ACTOS and ACTO*plus*. DPPs further contend that Defendants exacerbated the exclusivity by agreeing not to enter the ACTOS market until 20 months after the '777 patent expired on January 17, 2011. In DPPs' view, had the Generic Defendants continued the litigation against Takeda—for which trial was scheduled to begin in June 2010—those defendants would have won, and entered the market shortly after the '777 patent expired. By allegedly prolonging the start of 180-day exclusivity, and thus the corresponding

bottleneck for all subsequent filers, DPPs assert that the agreements are subject to antitrust scrutiny as outside the scope of the patents.

C. DPPs' Non-Reverse Payment Theory Lacks Legal Support

In their supplemental briefing, DPPs essentially argue that their theory that the settlement agreements restrained trade outside the scope of the Patents is supported by *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963). The Court disagrees.

Singer concerned cross-licensing agreements among three parties, each of which held patents on sewing machines that resulted in (1) the settlement of a so-called interference proceeding before the Patent Office to facilitate the issuance of a patent, despite the parties' evidence that the patent was invalid; and (2) the assignment of that patent, among others, to the one party in the best position of enforcing them—on behalf of all three parties—against competitors. "By aggregating patents in one control," to suppress competition for the benefit of *three* competitors, the parties' agreements restrained trade in a manner beyond the scope of the patent. 374 U.S. at 197.

DPPs allege that *Singer* is factually analogous to this case, because both purportedly involve a company entering into a series of transactions to rid themselves of competition. But under that logic, this case is factually analogous to nearly every antitrust case that involves a restraint of trade or monopolization claim. Contrary to DPPs' contention, the situation here is distinct from that in *Singer*. Among other differences, in *Singer*, the parties obtained rights outside the scope of the patents based on their joint efforts to procure a patent by withholding evidence that it was invalid. Here, however, the restraint in trade purportedly outside the scope of the Patents—the 180-day exclusivity period—was not obtained as the result of concerted conduct. That is, DPPs do not allege that the first generics conspired with Takeda to describe the patents as

drug product patents in the first instance, in order to unlawfully obtain the 180-day exclusivity. Their theory, by contrast, is that Defendants conspired to choose a date for generic entry of ACTOS that prolonged the 180-day exclusivity period—which the Generic Defendants allegedly knew was the result of *Takeda's* false representations to the FDA. This purported conspiracy is materially distinct from *Singer* because, as discussed further below, it occurs in the context of settling litigation in which non-frivolous claims of infringement are being asserted against the defendants. DPPs do not cite any other case that could provide even a colorable basis to support their settlement-with-knowledge-of-Orange-Book-fraud theory.

In short, DPPs' non-reverse-payment theory as to how the settlement agreements constitute unreasonable restraints of trade is truly novel: no other court, as far as this one can tell, has ever endorsed it.

D. DPPs Fail to Persuade the Court to Adopt their Non-Reverse Payment Theory

The fact that no other court has endorsed DPPs' non-reverse-payment theory does not, of course, preclude this Court from doing so. But DPPs' theory nonetheless fails because it seeks to extend antitrust scrutiny in a manner inconsistent with the principles of *Actavis.*

FTC v. AbbVie Inc., helps explain why this is the case. *See* 107 F. Supp. 3d 428 (E.D. Pa. 2015). There, the FTC asserted that two Paragraph IV settlements reached on the same day constituted unlawful restraints of trade because the generic defendant (which happened to be Teva) allegedly *knew* that the litigation was a sham all along—i.e., that it was subjectively and objectively baseless. *See id.*; *see also generally Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993) (discussing sham litigation claims). In the first agreement, the patentees permitted Teva to market the generic product that was the subject of the litigation six years before the relevant patent expired. In the second, the brand agreed to supply Teva with an

authorized generic version of a drug that was *not* the subject of the litigation for a four-year term, with royalty terms allegedly more favorable than in the market. The court ultimately held that if these settlements could be subject to antitrust scrutiny under a theory that Teva knew the litigation was groundless, the generics would be faced with the following choice: litigate the action to its conclusion "with all the attendant expense and use of judicial resources," or risk antitrust liability based upon its unproven view of the sham nature of the suit. 107 F. Supp. 3d at 438. In that court's view, "[s]uch a result would undermine the salutary public policy favoring settlements far beyond the holding of *Actavis*." *Id.*

This reasoning applies with equal force here. Permitting antitrust scrutiny of Paragraph IV settlements based on a generic's alleged awareness of the impropriety of an Orange Book listing—where the generic played no part in the listing decision in the first place—would also impose an untenable choice on generic defendants: litigate their patent claims to the end, or risk antitrust liability by settling on terms that even *Actavis* endorsed—based on the possibility that the *brand's* patent descriptions were improper. This too would deter generics from entering into Paragraph IV settlements in a manner far beyond that deemed acceptable in *Actavis*.

DPPs' attempts to distinguish *AbbVie* are unavailing. They argue that this case is unique because, at the time of the settlements, Takeda was no longer even asserting the drug product claims of the Patents in the litigation. Indeed, Takeda appears to have withdrawn its infringement claims, predicated on the drug product claims of the Patents, as early as December 2005. *See* DPPs' Supp. Opp. at 18 n.88. DPPs assert that this demonstrates that the settlements reached beyond the scope of the Patents, because there was in fact no need to settle Takeda's drug product claims. But as explained in *End Payor I*, regardless of whether the drug product claims were being asserted when the parties settled, "the Generic Defendants may nonetheless have been found liable for

inducing infringement of those patents' method of use claims." 2015 WL 5610752, at *23. Contrary to DPPs' suggestion that those claims were meritless, Judge Cote had denied Actavis' motion to dismiss on this basis, as well as a motion for judgment on the pleadings of non-party Sandoz Inc. The Generic Defendants were thus faced with the choice of whether to settle Takeda's claims of infringement of the method-of-use claims, or keep litigating and potentially lose—thereby risking a ruling that their proposed label would induce infringement of the Patents' method-of-use claims, and an injunction preventing them from entering the market. *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 663 F.3d 1042 (Fed. Cir. 2010) (affirming preliminary injunction enjoining generic from marketing brand's product even where generic submitted Section viii statements carving out patented uses because generic's label may still have induced infringement of patented uses).

The Generic Defendants chose to settle on terms endorsed by *Actavis*, by agreeing to enter the market at a later date. *See Actavis*, 570 U.S. at 153-154. While they may have not been entitled to benefit from the 180-day exclusivity period, at the time they settled, the damage had already been done by Takeda: in response to Takeda's 2010 statements, the FDA mandated that all pending ANDAs include Paragraph IV certifications. Takeda's contention that the generics should have forfeited the exclusivity, or entered the market immediately so as not to prolong it, is tantamount to asserting that the generics were required to agree to the most pro-competitive settlement under the circumstances. That is not the law: *Actavis* requires only that the parties to a patent litigation settlement refrain from unlawfully restricting competition, not that they maximize competition. *See End Payor I*, 2015 WL 5610752, at *16; *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 408-409 (3d Cir. 2015) ("*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible.").

Moreover, not only would DPPs' theory further disincentivize settlement in a manner beyond that of *Actavis*, it could also disincentivize generics from seeking to assert de-listing counterclaims. If a generic asserted such a counterclaim and then subsequently settled—even if it believed that its counterclaim had only a moderate chance of success—under DPPs' theory, the generic may face antitrust liability based on allegations that it plausibly *knew* those descriptions were false—given that is the litigation position it took. Such a result would run contrary to the purposes of the counterclaim provision designed to curb brand companies' abuses of Orange Book listings. *See Caraco Pharm. Labs., Ltd.*, 566 U.S. at 408–09 (explaining that the counterclaim provision was Congress' response to brand companies' exploitation of the fact that the FDA does not police the propriety of Orange Book listings).

The Court thus declines to conclude that DPPs' settlement-with-knowledge-of-Orange-Book-fraud theory can subject Paragraph IV settlements to antitrust scrutiny. Because DPPs do not allege that the 180-day exclusivity was obtained as the result of joint conduct before the FDA, the terms of the agreements to which the generics agreed do not otherwise form a basis for antitrust scrutiny.

E. DPPs Do Not Adequately Allege that the First Generics Knew The Relevant Patent Descriptions Were False

In any event, even if the Court accepted DPPs' theory as providing a basis for antitrust scrutiny here, DPPs fail to allege any facts to support a plausible inference that the first generics knew that the description of the Patents as drug product patents (and Takeda's statements to the FDA confirming their accuracy) were false. As such, they have failed to plead the necessary facts to sustain their theory that the settlements violated the antitrust laws.

DPPs allege that the first generics knew that the Patents were described as drug product patents when the first generics filed their ACTOS ANDAs in 2003. With respect to Mylan and

Ranbaxy, DPPs assert that because those generics submitted split certifications when they filed their ANDAs—even though the Orange Book then displayed that the Patents were described as method-of-use patents only—Mylan and Ranbaxy must have known that Takeda had described the Patents as drug product patents. But the Second Circuit rejected this theory as implausible in *End Payor II*, 848 F.3d at 98. DPPs' allegations here include no additional facts making this theory any more plausible. And even if they did, the notion that Mylan and Ranbaxy knew the Patents were described as drug product Patents in 2003 says nothing about whether they knew those descriptions were false or improper.

With respect to Actavis, DPPs' Complaint includes allegations not pled in the *End-Payor* action to support their claim that Actavis knew of the Patents' drug product descriptions shortly after it filed its ANDA in 2003. But again, even assuming those allegations are sufficient to plausibly allege that Actavis knew how the patents were described at the time, this says nothing about whether it knew those descriptions were false.

DPPs also allege that the first generics knew how the Patents were described by the time the FDA accepted their ANDAs as complete. This Court already rejected such a theory as too speculative, however, when only partially granting EPPs' motion to amend their complaint. *See End Payor*, 2018 WL 840099, at *4. This is because it relies on the FDA's purported policy of telling generics if they had improperly filed certifications with their ANDAs and then requiring them to fix those certifications. Although the FDA may have followed such a policy with respect to Actavis, it did not do so with respect to Teva—suggesting that at best the FDA *sometimes* examined the propriety of the generics' certifications. Yet again, even accepting such a theory, the first generics' knowledge of the Patents' descriptions says nothing about their knowledge as to the accuracy of those descriptions.

The same is true as to DPPs' allegations that the first generics knew of the drug product descriptions when Takeda publicly confirmed them in January 2010 in response to the Sandoz citizen petition. DPPs' assertion that it follows that the first generics knew these descriptions were false or improper is plainly speculative in the absence of any facts to support such a theory.

It is true that DPPs contend that it is practically certain that the first generics *read* the patents in order to prepare their Paragraph IV certifications. But this misses the point: the fact that the first generics may have read the Patents does not plausibly establish that they knew the descriptions were false. As is evident from this Court's most recent opinion in *End Payor III*, to conclude that the patent descriptions were false requires an in-depth legal analysis. While DPPs allege that the first generics are "regulatory savvy," that is not a fact that renders the assertion that they knew the descriptions were false any less speculative. "Plaintiffs are due all reasonable inferences, but they must allege some factual basis from which to make those inferences." *End Payor II*, 848 F.3d at 99. Because DPPs fail to do so, they cannot sustain their antitrust claims against the first generics even pursuant to their non-reverse-payment theory.

F. DPPs Do Not Adequately Allege that Teva's Settlement Caused Antitrust Injury

With respect to Teva, even if the Court accepted DPPs' settlement-with-knowledge-of-Orange-Book-fraud theory, DPPs still fail to adequately allege that Teva's settlement with Takeda caused antitrust injury.

Unlike the first generics, Teva was not a first-filer for ACTOS (nor ACTO*plus*) and thus was never entitled to the 180-day exclusivity period. Pursuant to the Act, the FDA could not grant final approval to Teva's ANDA until after the first filers' 180-day exclusivity period expired. *See* 21 U.S.C. § 355(j)(5)(B)(iv). In other words, to the extent Teva settled with Takeda, it could not have agreed to enter the market with its *own* product until six months after the first-filers did, i.e.,

on August 17, 2012.[3] As such, Teva contends that in order to have been able to enter the market any earlier than August 17, 2012, the following events would have had to occurred: (1) Teva would have won its litigation with Takeda with respect to all relevant patents; (2) the Federal Circuit would have affirmed Teva's win on appeal; and (3) the Federal Circuit would have denied any petitions for rehearing or rehearing *en banc*, and issued its mandate; *all within 20 months*—that is, by February 17, 2012. This is because, as Teva explains, the Federal Circuit's mandate would have triggered the 180-day exclusivity period of the first-filers. It therefore would need to have issued 180 days prior to August 17, 2012, for Teva to have been able to enter the market by February 17, 2012.

DPPs respond that because Teva had sought leave to amend its answer to assert a de-listing counterclaim before it settled, Teva could have eventually won on its counterclaim which, they allege, would have corrected the Patent descriptions, and resulted in the loss of the 180-day exclusivity period of the first filers. Under that theory, in order for Teva to enter the market before August 17, 2012, the following would have had to occurred: (1) Teva would have been granted leave to amend its counterclaim; (2) Teva would have won on the counterclaim; (3) the Federal Circuit would have affirmed and issued its mandate; and (4) the FDA would have granted Teva final approval of its ANDA—all before August 17, 2012.

Under either of these scenarios, DPPs fail to plausibly allege that these events would have occurred within the requisite time frame. As Teva rightly argues, many courts—including this one—have found that "assumptions regarding success at trial are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise." *End Payor I*, 2015

[3] Through the settlement, Teva was able to enter the market at the same time as the first-filers because it did so as an authorized generic—that is, Takeda granted Teva a license to sell Takeda-manufactured tablets under Teva's label. As previously noted, the 180-day exclusivity period does not bar authorized generics from entering the market at the same time.

WL 5610752, at *27; *AbbVie*, 107 F. Supp. 3d at 437 (rejecting FTC's allegations that the court would likely rule in favor of Teva on its sham litigation as speculative). DPPs fail to allege any such facts. Accordingly, they cannot sustain their claims against Teva based on its settlement agreement with Takeda.[4]

III. Overarching Conspiracy Claims

Because DPPs have failed to allege that the agreements constituted restraints of trade in violation of § 1, their claim for an overarching conspiracy to restrain trade fails as well. *See AstraZeneca AB v. Mylan Labs., Inc.*, No. 00 CIV. 6749, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010) (dismissing conspiracy in restraint of trade claim based on failure to adequately allege predicate acts in restraint of trade), *aff'd sub nom. In re Omeprazole Patent Litig.*, 412 F. App'x 297 (Fed. Cir. 2011).

Similarly, DPPs' overarching claim of a conspiracy to monopolize based on the settlement agreements also fails, because DPPs have not established that the agreements provide a basis for a monopolization claim—for largely the same reasons that they have not established that the agreements constitute a restraint of trade. As explained in *End Payor I*, the settlement agreements did not result in a further concentration of Takeda's monopoly power. And DPPs have failed to persuade the Court that its non-reverse-payment theory can otherwise establish that the

[4] To be clear, the Second Circuit and this Court have previously held that Takeda's statements to the FDA in January 2010 concerning the Patents' Orange Book descriptions plausibly caused Teva's delay in generic market entry. Under this theory, by contrast, those statements caused the FDA to cause Teva to file Paragraph IV certifications as to the drug product claims, after which Teva settled by accepting (among other things) a license to market an authorized-generic version of ACTOS on August 17, 2012 or the date another generic version of ACTOS entered the market if earlier. Absent those statements, DPPs plausibly allege that Teva would have stuck with its Section viii statements and obtained FDA approval to enter the market soon after the '777 patent expired. This casual mechanism is supported by the facts alleged in DPPs' Complaint—unlike the alleged causal mechanism as to how Teva's 2010 *settlement* with Takeda further delayed Teva's market entry. In other words, while DPPs plausibly allege that Takeda's unilateral conduct delayed Teva's entry, they fail to do the same with respect to Takeda and Teva's joint conduct in entering the settlement. As such, DPPs' restraint of trade claim against Teva is dismissed for failure to allege antitrust injury.

agreements—or DPPs' alleged overarching single agreement—unlawfully perpetuated Takeda's monopoly in the ACTOS and ACTO*plus* drug markets. DPPs' conspiracy claims are thus dismissed.

III. Leave to Amend

Finally, DPPs' request for leave to amend the Complaint is denied. Although courts should "freely give leave [to amend] when justice so requires," they need not grant leave to amend if the amendments would be futile or cause undue delay, among other things. Fed. R. Civ. P. 15(a)(2); *see Passlogix, Inc. v. 2FA Tech., LLC*, 708 F. Supp. 2d 378, 407 (S.D.N.Y. 2010). Despite the fact that DPPs have had two prior opportunities to amend in light of the relevant decisions in the *End-Payor* cases, they seek leave to amend again because Defendants purportedly did not provide DPPs with the settlement agreements until after the Second Amended Complaint was filed. Be that as it may, amendment would still be futile, because the problem with DPPs' claims based on those settlement agreements is substantive: "better pleading will not cure it." *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir.2000).

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss Counts II through VIII of the Complaint is GRANTED. Takeda's motion to dismiss Count I is DENIED. The Clerk of Court is directed to lift the stay of this case.

SO ORDERED.

Dated: October 8, 2019
New York, New York

Ronnie Abrams
United States District Judge