UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END PAYOR ANTITRUST LITIGATION

No. 13-CV-9244 (RA)

OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

This case concerns the purportedly anticompetitive effects of patent infringement litigation settlements between the brand manufacturer of prescription drugs used to treat diabetes and the brand's generic competitors. Plaintiffs are indirect purchasers of the drugs and bring this consolidated purported class action[1] on behalf of themselves and all others similarly situated against Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"), Mylan Inc. and Mylan Pharmaceuticals Inc. (together, "Mylan"), Actavis PLC (formerly known as "Actavis, Inc.") and Watson Laboratories, Inc. (together, "Actavis"), Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc. (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together "Teva"). Plaintiffs allege that Takeda (the "Brand"), Mylan, Actavis, and Ranbaxy (the "Generic Defendants"), and Teva (the "Authorized Generic") engaged in anticompetitive conduct designed to control and delay competition in the market for the diabetes drugs sold by Takeda under the brand names ACTOS

[1] Pursuant to Magistrate Judge Ellis's May 20, 2014 Order, the following cases were consolidated for pretrial purposes under Federal Rule of Civil Procedure 42(a): 1:13-CV-09244; 1:13-CV-09250, 1:14-CV-00116, 1:14-CV-00644, 1:14-CV-01493, 1:14-CV-02532, 1:14-CV-01661, 1:14-CV-02617, 1:14-CV-01691, 1:14-CV-01788, 1:14-CV-02424, 1:14-CV-02378, 1:14-CV-02137, 1:14-CV-02846. *See* Dkt. 46.

and ACTO*plus* met in violation of various state antitrust, consumer protection, and unjust enrichment laws.[2]

Before the Court are Defendants' Motions to Dismiss the Consolidated Amended Class Action Complaint ("CAC") for failure to state a claim and on standing grounds. Dkt. 122, 124, 125, 131. For the reasons set forth below, the motions are granted.

BACKGROUND[3]

I. Facts of the Case

A. Industry Background

Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), a branded drug manufacturer ("brand") must obtain approval from the Food and Drug Administration ("FDA") to sell a new drug product by filing a New Drug Application ("NDA"). The NDA must include information regarding the safety and effectiveness of the drug, as well as any applicable patents. 21 U.S.C. § 355(a), (b). At the time Takeda submitted its NDA for ACTOS, the relevant statute required it to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." CAC ¶ 65 (citing 21 U.S.C. § 355(b)(1) (1999, 2002)). For patents that claimed a drug substance or product, the relevant FDA regulations provided that the NDA applicant submit

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[2] It is undisputed that because Plaintiffs are indirect purchasers, they may not recover overcharges under federal antitrust law or under the laws of those states which follow the rule of *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). Accordingly, Plaintiffs have standing to assert violations of only the state antitrust laws that do not follow *Illinois Brick*, and any claims under the laws of states following *Illinois Brick* fail as a matter of law.

[3] The facts are taken from the CAC and are presumed to be true for the purposes of this motion to dismiss. The Court also considers the settlement agreements referenced in the CAC and filed under seal, in accordance with its prior ruling. Dkt. 118. *See also See In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013) ("In adjudicating a motion to dismiss, a court may consider . . . any document upon which the complaint heavily relies.") (quotations and citation omitted).

"information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product." 21 C.F.R. § 314.53(b) (1999, 2002).[4] For any approved new applications, the patent information provided by the NDA applicant is published by the FDA in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

To facilitate the approval of generic drugs, under the Hatch-Waxman Amendments to the FDCA, a manufacturer seeking to market a generic version of a previously approved brand name drug need only file an Abbreviated New Drug Application ("ANDA"). The ANDA relies on the scientific findings included in the original NDA, but must establish that the generic drug contains the same active ingredients, route of administration, dosage, and strength, and is the "bioequivalent" of the listed drug. 21 U.S.C. § 355(j)(2).

The ANDA-filer is also required to consult the Orange Book and provide the FDA with information regarding the brand's patents. Any ANDA submitted must contain "an appropriate certification for each listed patent." 21 C.F.R. § 314.53(f). This requirement applies even where there is disagreement as to the accuracy of the patent information listed by the brand for a particular drug product.

Where there are no applicable patents, or the patents have expired or will expire prior to the ANDA's approval, the generic manufacturer may simply file a certification to that effect. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III). But if those provisions do not apply, the generic must do one

[4] The current version of this provision provides: "For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application . . . For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product . . that is described in the pending or approved application." 21 C.F.R. § 314.53(b) (2014).

of two things to obtain approval. One option is to submit a "Section viii Statement," which asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents. *See* § 355(j)(2)(A)(viii). This option "is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012). Accordingly, the generic will propose a label that "'carves out' from the brand's approved label the still-patented methods of use." *Id.*; 21 C.F.R. § 314.94(a)(8)(iv). If the FDA accepts the label, the generic can place the drug on the market for those approved uses only. *Caraco Pharm. Labs.*, 132 S. Ct. at 1677. The FDA will not, however, approve an ANDA if the generic's proposed carve-out label overlaps with the brand's use code; notably, that use code is provided by the brand and is not independently reviewed by the FDA. *Id.* (citing 68 Fed. Reg. 36682-36683 (2003)). "Thus, whether section viii is available to a generic manufacturer depends on how the brand describes its patent." *Id.*

In the alternative, the generic may file a "Paragraph IV Certification," providing that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The generic will use this option if it wants to market the drug for all uses (instead of carving out the still-patented uses), or if it cannot adopt a viable carve-out. *Caraco Pharm. Labs.*, 132 S. Ct. at 1677. Where a patent contains both a product and a method of use claim, the generic may file a Paragraph IV Certification as to the product claim and a Section viii Statement (and proposed "carve-out" label) as to the method of use claim. *See Watson Labs., Inc. v. Sebelius,* 2012 WL 6968224, at *4 n.3 (D.D.C. Oct. 22, 2012).

The filing of a Paragraph IV Certification is treated under the Hatch-Waxman Act as an act of infringement of the brand's patent, and gives the brand the immediate right to sue. *See* 35

U.S.C. § 271(e)(2)(A). Once the brand sues, the FDA generally cannot approve the ANDA until 30 months pass or the litigation is resolved in favor of the generic. *See* 21 U.S.C. 355(j)(5)(B)(iii).

Generic manufacturers challenging the validity of a patent claimed by the brand have recourse under the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"). The MMA authorizes a generic sued for patent infringement to "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." 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see also Caraco Pharm. Labs.*, 132 S. Ct. at 1678. If successful, the generic may thus obtain a judgment directing the brand to remove the patent information blocking the FDA's approval of the generic drug product.

In recognition of the uncertainty and expense a generic manufacturer faces when initiating a patent infringement suit, the Hatch-Waxman Act provides the first generic filer of a Paragraph IV Certification with a special benefit: the FDA may not approve a subsequent generic ANDA until 180 days after that so-called first-filer enters the market. 21 U.S.C. § 355 (j)(5)(B)(iv). If there are multiple first-filers, they share this exclusivity period. *Id.* During that period, no other generics may enter the market. This exclusivity period does not, however, preclude entry by so-called "authorized generics," which are sold by the brand or through a licensed third-party generic drug manufacturer. CAC ¶ 85.

Despite the protections provided by the statutory scheme to generic manufacturers, Plaintiffs allege that brand manufacturers may nonetheless "game the system" by suing generic drug manufacturers under the Hatch-Waxman Act not to enforce a valid patent, but with the goal of delaying generic drug competition. CAC ¶ 75. Prior to the enactment of the MMA, the first

generic filer could assist the brand manufacturer by delaying not only its own market entry, but the entry of all other generics as well in exchange for payments from the brand. *Id.* ¶ 76. After the passage of the MMA, however, a generic ANDA applicant forfeits its 180-day exclusivity period under certain circumstances, such as if the applicant fails to obtain tentative approval from the FDA within 30 months of filing the ANDA. *Id.* ¶¶ 77–78; 18 U.S.C. § 355(j)(5)(B)(iv)(D). According to Plaintiffs, however, the MMA does not prevent brands and generics from unlawfully structuring their settlement agreements so that there is no judgment invalidating the brand's patent or finding it not infringed, but the first-filer generic's 180-day exclusivity period is left intact. *Id.* ¶ 79. In these cases, they assert that any subsequent generic ANDA applicants must obtain a judgment that all patents subject to the first-filer's ANDA are invalid or not infringed in order to enter the market before the 180-day period expires. *See id.* This barrier to entry reduces generic competition.

B. ACTOS and ACTO*plus*

ACTOS and ACTO*plus* met ("ACTO*plus*") are pioglitazone hydrochloride medications prescribed to treat Type 2 diabetes. ACTOS is prescribed as a monotherapy treatment (by itself), or in combination with sulfonylurea, metformin, or insulin. ACTO*plus*, which contains pioglitazone hydrochloride and metformin, is prescribed to improve blood sugar control in adults with Type 2 diabetes who are already taking ACTOS and metformin separately, or are taking metformin alone. CAC ¶ 2. In 1999, the FDA approved Takeda's NDA for ACTOS for the use of improving glycemic control as a monotherapy or in combination with a sulfonylurea, metformin, or insulin and in 2005, the FDA approved Takeda's NDA for ACTO*plus*. *Id.* ¶¶ 89, 123.

Together, ACTOS and ACTO*plus* generated over three billion dollars in annual sales for Takeda by 2011. *Id.* ¶ 3. Plaintiffs claim that to prevent generic drug manufacturers from depleting those profits, Takeda devised a "multi-part scheme which it enticed its would-be generic competitors to join." *Id.* ¶ 4.

1. The ACTOS Patents

a. The ACTOS NDA and Orange Book Listing

Pursuant to the FDA's requirements, when Takeda filed its NDA for ACTOS, it was required to list all patents that "claim[ed] the drug" and all patents that "claim[ed] a method of using the drug" for publication in the Orange Book. *See* 21 U.S.C. § 355(b)(1). Takeda listed three patents as claiming the ACTOS drug: Nos. 4,687,777 ("777 patent"), 5,965,584 ("584 patent") and 6,329,404 ("404 patent"). The 584 and 404 patents also claimed methods of using ACTOS.

There is no dispute that the 777 patent claimed the active ingredient in ACTOS, pioglitazone hydrochloride. *See id.* ¶¶ 9, 90. Nor is there any dispute that the 584 and 404 patents were properly listed as claiming methods of using ACTOS. *See id.* ¶¶ 92, 93. Plaintiffs allege, however, that Takeda's description of the 584 and 404 patents as claiming the ACTOS drug product was false and misleading because the drug composition claimed by those patents contained not only pioglitazone hydrochloride, but additional drug components. *Id.* In particular, the 584 patent claims a drug product consisting of pioglitazone hydrochloride and a biguanide (metformin), and the 404 patent claims a drug product consisting of pioglitazone hydrochloride and an insulin secretion enhancer. *Id.* ¶¶ 6, 92, 93. Accordingly, the 584 patent was also listed by Takeda in the Orange Book for ACTO*plus* (which contains metformin), and the 404 patent was listed for Ducetact (which contains an insulin secretion enhancer). *Id.*

Because the patents purport to claim the drug compositions of these other products, Plaintiffs posit that Takeda's listing of the 584 and 404 patents as patents claiming the ACTOS drug—which does not contain either a biguanide or insulin secretion enhancer—was inaccurate and misleading. The inclusion of those patents is significant, they argue, because although the 777 patent claiming the active ingredient in ACTOS expired on January 17, 2011, *id.* ¶ 9, the 584 and 404 patents did not expire until June 19, 2016, *id.* ¶¶ 92, 93. Consequently, the purportedly inaccurate listing of the 584 and 404 patents in the Orange Book, they say, delayed generic entry past the 2011 expiration date of the 777 patent, when Plaintiffs assert generic entry should have occurred. *Id.* ¶ 9.

More specifically, Plaintiffs allege that by listing the 584 and 404 patents as drug component patents for ACTOS, Takeda ensured that the first generic manufacturer to file an ANDA for ACTOS would be required to submit a Paragraph IV Certification with regard to those patents, which entitled the first-filer to 180 days of generic marketing exclusivity. During that 180 day period, no other generics were permitted to enter the market, which in Plaintiffs' view, created a "bottleneck" on FDA approval of other ACTOS generic products until the first generic filer entered the market. *Id.* ¶ 7.

According to Plaintiffs, if Takeda had not improperly described the 584 and 404 patents as claiming the ACTOS drug product, "no ANDA filer would (or could) have submitted a Paragraph IV Certification for ACTOS." *Id.* ¶ 102. As a result, Defendants Mylan, Ranbaxy, and Actavis could have entered the market—presumably after submitting Section viii Statements and having "carve out" labels approved—as soon as the 777 patent expired on January 17, 2011. Moreover, because no 180-day period of exclusivity would have attached to their entry, additional generics could have simultaneously entered the market. *Id.* ¶ 103.

b. The ACTOS ANDAs

In July 2003, Defendants Mylan, Alphapharm (since acquired by Mylan), Ranbaxy, and Actavis (formerly Watson), each filed an ANDA for generic versions of ACTOS with Paragraph IV Certifications as to the 584 and 404 patents and Section viii Statements as to the method of use patents. *Id.* ¶¶ 105–108. Mylan (and Alphapharm) also made a Paragraph IV Certification as to the 777 patent, but Actavis and Ranbaxy filed Paragraph III Certifications instead, indicating that they would not seek final FDA approval until the 777 patent expired. *Id.*; Def. Joint Mem. at 7.

Subsequently, the FDA determined that all generic manufacturers seeking to market generic ACTOS were required to submit Paragraph IV Certifications as to each of the three patents. Prior to the expiration of the 777 patent, a non-party generic manufacturer submitted a Citizens Petition to the FDA regarding Takeda's listing of the 584 and 404 patents in the Orange Book as patents claiming the ACTOS drug product. *Id.* ¶ 99. On March 15, 2010, after Takeda confirmed to the FDA that the patents claimed both the drug product and methods of using ACTOS, the FDA issued a ruling concluding that all ANDA filers seeking approval to market generic ACTOS before the expiration of the 584 and 404 patents were required to submit Paragraph IV Certifications with respect to those patents. *Id.* ¶¶ 100–101. Thereafter, no generic manufacturer could obtain FDA approval of its ACTOS ANDA by submitting Section viii Statements as to the 584 and 404 patents.

2. ACTOS Patent Infringement Litigation

On October 17, 2003, in response to the ANDA filings, Takeda filed suits in this district against Mylan, Ranbaxy, and Actavis, alleging that their generic products would infringe the drug product claims of the 584 and 404 patents, and induce infringement of those patents' methods of use claims as well as certain of the eight additional method of use patents listed for ACTOS. *Id.* ¶ 109. The trial judge, the Honorable Denise Cote, first considered whether the 777 patent was

valid and infringed by Mylan/Alphapharm.[5] Judge Cote ruled in favor of Takeda, concluding that the 777 patent was valid and that Mylan/Alphapharm had engaged in "exceptional" misconduct and had filed their Paragraph IV Certifications in bad faith. *See Takeda Chem. Indus. Ltd. v. Mylan Labs., Inc.*, 459 F. Supp. 2d 227 (S.D.N.Y. 2006), *subsequent determination,* 2007 WL 840368 (S.D.N.Y. Mar. 21, 2007), *aff'd*, 549 F.3d 1381 (Fed. Cir. 2008). Judge Cote awarded Takeda over $16.8 million dollars in attorney's fees and entered a limited final judgment in its favor; this judgment was later affirmed by the Federal Circuit. *Id.*

The parties then began additional discovery and settlement negotiations regarding the 584, 404, and method of use patents. *See* CAC ¶ 110. Ultimately, Takeda settled the litigations. Plaintiffs claim it did so in order to "protect its monopoly." *Id.* ¶¶ 110–111.

On or about March 15, 2010, Takeda entered into individual settlement agreements with the Generic Defendants, pursuant to which Takeda agreed to immediately dismiss its patent infringement actions and the Generic Defendants agreed to drop their challenges to Takeda's patents. Pursuant to the agreements, Mylan, Actavis, and Ranbaxy were each granted a non-exclusive license by Takeda to enter the market with a generic ACTOS product on August 17, 2012—almost four years prior to the expiration of the 584 and 404 patents. *See* Generic ACTOS Agreements, Def. Exs. 1, 2, 4. Ranbaxy's agreement additionally included a supply provision, which allowed Ranbaxy, at its option, to purchase the ACTOS drug product from Takeda pursuant to a fee schedule included in the agreement. Def. Ex. 1, Ranbaxy Agreement at 10. 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. Def. Exs. 1, 2, 4. Neither the FTC nor the Department of Justice objected to the settlements.

[5] Actavis and Ranbaxy's ANDAs indicated that they were not seeking to market generic ACTOS until after the 777 patent expired. *See* Def. Joint Mem. at 7.

Plaintiffs allege that as part of these three settlements, Takeda made several forms of unlawful "payments" to the Generic Defendants, including (1) "acceleration clauses" in each agreement providing that in the event that any other ACTOS generic entered the market before August 17, 2012, Mylan, Ranbaxy, and Actavis would also be able to enter at such date; (2) a license for Ranbaxy to enter the market with a generic form of ACTO*plus* 180 days after the first ANDA filer (Mylan) entered the market; and (3) a license for Actavis to enter the market with generic ACTO*plus* at the same time as Ranbaxy. *Id.* ¶¶ 114–116; *see also* Def. Exs. 1, 2, 4.[6]

Pursuant to the so-called acceleration clauses, Mylan, Ranbaxy, and Actavis' entry dates for ACTOS would be moved up from August 17, 2012 under certain circumstances. *See* Def. Exs. 1–4. The terms triggering earlier entry varied slightly under the respective agreements, but generally, they provided that Mylan, Ranbaxy, and Actavis could enter the market as early as any other generic did. *See id.*[7]

Following the settlements, at least seven other generic drug manufacturers who had filed ANDAs for generic ACTOS entered into joint stipulations of dismissal of their own infringement actions with Takeda and purportedly agreed to delay their entry into the market until 180 days after Mylan, Ranbaxy, and Actavis entered the market. CAC ¶¶ 120–122.

Plaintiffs allege, however, that had the cases not settled, the Generic Defendants would have prevailed in the infringement actions because the 584 and 404 patents did not claim the ACTOS drug product, but only claimed a method of using ACTOS. As a result, Plaintiffs claim, the Generic Defendants would have been able "to enter the market on or about January 17, 2011"—

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[6] As discussed further below, by separate agreement, Mylan, as the first-filer for ACTO*plus*, was also granted a license to enter that market no later than December 14, 2012. Def. Ex. 3, Mylan ACTO*plus* Agreement.

[7] Earlier entry was permitted, for instance, if the date of first commercial marketing of a generic ACTOS product by a third party under an FDA approved ANDA, Ex. 1, Ranbaxy Agreement at 7, or a final decision holding that the adjudicated claims of the licensed patents for ACTOS were invalid, Ex. 2, Mylan ACTOS Agreement at 9 occurred prior to the dates fixed by the agreements.

the date the 777 patent expired—and other generics would have entered the market earlier as well. *Id.* ¶¶ 9, 163.

3. ACTO*plus* Litigation

Plaintiffs further allege that Takeda employed the same strategy with ACTO*plus*. On June 23, 2008, Mylan informed Takeda that it filed an ANDA for a generic version of ACTO*plus* with a Paragraph IV Certification as to the 584 patent and certain method of use patents. *Id.* ¶ 125. As the first ANDA filer for ACTO*plus*, Mylan was eligible for the 180-day exclusivity period. *Id.* ¶ 12. On August 5, 2008, Takeda sued Mylan for infringing the 584 patent. *Id.* ¶ 126. Although Plaintiffs contend that Takeda sued Mylan "[w]ithout regard to whether the lawsuits had legal merit," *id.* ¶ 11, they also concede that the 584 patent claimed for ACTO*plus* covered the drug's components, *id.* ¶¶ 6, 127.

Nevertheless, Plaintiffs allege that Takeda made "large, unjustified payments" to Mylan to settle the ACTO*plus* litigation. *Id.* ¶ 12. Mylan agreed to drop its challenge to Takeda's patents and to stay out of the generic ACTO*plus* market until December 14, 2012, or August 17, 2012 if Takeda's sales of ACTO*plus* fell below a certain threshold. *Id.* ¶ 130. As with the ACTOS agreement, in the event that any other generic entered the market first, Mylan would be permitted to enter at the same time. *Id.* ¶ 132. According to Plaintiffs, Takeda's ACTO*plus* agreement with Mylan was contingent on the terms of their settlement of the ACTOS patent litigation. *Id.* ¶ 133. Neither the FTC nor the Department of Justice objected to the ACTO*plus* settlement.

By entering into the settlement, Plaintiffs assert, Mylan protected its 180-day exclusivity period for ACTO*plus* and prevented at least four other generics from entering the market until that period concluded. *Id.* ¶¶ 135–37. After Mylan settled, these generics entered into their own stipulations of dismissal with Takeda, agreeing to delay entry until 180 days after Mylan entered.

Id. ¶ 138–39. Plaintiffs allege that if not for the settlement agreement between Mylan and Takeda, generic manufacturers of ACTO*plus* would have been able to compete as early as February 25, 2011. *Id.* ¶ 163. The CAC cites to no point of reference for this date, which appears inconsistent with the 584 patent's expiration date in June of 2016.

4. Teva – The Licensed Generic

On or about July 14, 2004, Teva, another generic manufacturer, also submitted an ANDA for a generic version of ACTOS. *Id.* ¶ 141. Teva filed a Section viii Statement as to each of the 584 and 404 patents, attesting that it did not seek FDA approval for a method of use covered by those patents. *Id.* As required, the Section viii Statements asserted that Teva's label for generic ACTOS would "carve out" information regarding methods of using ACTOS in combination with a biguanide or an insulin secretion enhancer—the methods of use claimed by the 584 and 404 patents—or other uses covered by Takeda's method of use patents. *Id.* Because no Paragraph IV Certification was filed, the ANDA filing did not immediately trigger an infringement lawsuit by Takeda. *Id.* ¶ 143.

On April 14, 2009, Teva filed an ANDA with regard to a generic version of ACTO*plus*, and included a Paragraph IV Certification as to the 584 patent and two additional patents held by Takeda. *Id.* ¶ 143. Takeda sued Teva on that basis on May 18, 2009, asserting that Teva's ANDA for ACTO*plus* intentionally infringed Takeda's patents, and that its ANDA for ACTOS intentionally induced infringement of the 584 and 404 patents and the method of use patents. *Id.* ¶ 144.

While the lawsuit was pending, the FDA issued its March 15, 2010 decision on the Citizen's Petition regarding Takeda's Orange Book listing for ACTOS, concluding that because the 584 and 404 patents included both drug product and method of use claims, it would not approve

any ACTOS ANDA without a Paragraph IV Certification. *Id.* ¶ 146. On March 30, 2010—after Takeda settled with the Generic Defendants—Teva filed a motion to amend its answer to add a counterclaim that, as to ACTOS, Takeda had improperly submitted patent information for the 584 and 404 patents, describing them as drug product patents claiming the ACTOS drug. *Id.* ¶ 147.

Had Teva succeeded on its counterclaim, Plaintiffs allege, it would not have been subject to the 180-day exclusivity period preserved by Takeda's settlement agreements with the Generic Defendants, and could have entered the market as early as January 17, 2011. *Id.* But Takeda and the Generic Defendants, they claim, sought to stop Teva from "unravel[ling] the anticompetitive schemes." *Id.* ¶ 13. Takeda and Teva thus began settlement negotiations, during which Takeda purportedly disclosed the existence of the acceleration clauses in its agreements with the Generic Defendants in order to dissuade Teva from entering the market before August 17, 2012. *Id.* ¶¶ 150–51.

Teva and Takeda entered into a settlement agreement on December 22, 2010, pursuant to which Teva agreed to drop its challenges to Takeda's patents for ACTOS and ACTO*plus*. *See id.* ¶ 153. In return, Takeda granted Teva licenses to launch authorized generic versions of ACTOS and ACTO*plus* during the first 180 days of generic marketing. *Id.* ¶¶ 155–56, 158–60; Def. Ex. 5, Teva Agreement. Teva also agreed to pay Takeda a royalty of seventy-five percent of its net profits on the authorized generic ACTOS and ACTO*plus* sales during that initial 180 day period. Def. Ex. 5, Teva Agreement Ex. B at 3. The agreement further provided non-exclusive, royalty-free licenses for Teva to market its own generic versions of ACTOS and ACTO*plus* after the first 180 days of generic marketing. *Id.* at 11, 14. Pursuant to the agreement, in the event that any other generic ACTOS or ACTO*plus* products entered the market before the date specified for Teva,

Teva's licensed entry date would be accelerated accordingly. CAC ¶¶ 157, 161. As with the other settlements, neither the FTC nor the Department of Justice objected to the Teva settlement.

Plaintiffs allege that this settlement prevented Teva from entering the ACTOS and ACTO*plus* markets as soon it otherwise would have, and thus that the settlement's terms constituted unlawful payments to delay generic entry. *Id.* ¶ 162.

C. Allegations Regarding Anticompetitive Effect

As to both the ACTOS and ACTO*plus* settlement agreements, Plaintiffs allege that they—the indirect purchaser classes—were deprived of "a marketplace in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments" and the "most cost efficient means of distribution" of the drugs. *Id.* ¶ 164. As a result of the agreements, the classes allegedly sustained substantial losses in the form of overcharges they paid for ACTOS, ACTO*plus* and their generic equivalents. *Id.* ¶ 165.

D. The ACTOS Class and ACTO*plus* Classes

The ACTOS class is defined as:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for ACTOS and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries . . . from January 17, 2011 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease.

Id. ¶ 166.

The ACTO*plus* class is defined as:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for ACTO*plus* and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by themselves, their families, or their members,

> employees, insureds, participants, or beneficiaries . . . from February 25, 2011 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease.

Id.[8]

LEGAL STANDARD

Pursuant to Rule 8 of the Federal Rules of Civil Procedure, Plaintiffs must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." In order to defeat a motion to dismiss pursuant to Rule 12(b)(6), Plaintiffs need not provide "detailed factual allegations," but their "obligation to provide the grounds of [their] entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Rather, the complaint must contain "sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "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." *Id.* Although "[t]he plausibility standard is not akin to a probability requirement . . . it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation omitted). Where a complaint pleads facts that are "merely consistent with" Defendants' liability, it "stops short of the line between possibility and plausibility" of Plaintiffs' entitlement to relief. *Twombly*, 550 U.S. at 557.

[8] Excluded from both classes are Defendants and their officers, directors, employees, corporate parents, subsidiaries, affiliates, representatives, and agents; federal or state governmental entities except for cities, towns or municipalities with self-funded prescription drug plans; all persons or entities that purchased ACTOS and/or ACTO*plus* or the AB-rated generic equivalent for purposes of resale and/or directly from Defendants or their affiliates; fully insured health care plans; any "flat co-pay" consumers whose purchases were paid, in part, by a third party payor, and those whose co-payment was the same regardless of the retail purchase price; Pharmacy Benefit Managers without capitation agreements; and the Court, Court personnel, and their family members. CAC ¶ 167.

DISCUSSION

I. Reverse Payment Claims

The central issue in this case is whether the terms of the settlement agreements between Takeda and the generic manufacturers are subject to antitrust scrutiny. Plaintiffs allege in Counts 3 to 6 that Takeda unlawfully conspired with the Generic Defendants and Teva, delaying generic competition in the ACTOS market through their settlement agreements regarding ACTOS. CAC ¶¶ 247–282. Plaintiffs further allege in Counts 8 and 9 that Takeda unlawfully conspired with Mylan and Teva to delay generic competition in the ACTO*plus* market. *Id.* ¶¶ 292–309. Although Plaintiffs sue under a variety of state statutes, the parties rely on the legal standards set forth in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), and its progeny for evaluating a reverse payment settlement, and the Court will do the same. *See* Pl. Opp. at 1; Def. Joint Mem. at 12.[9]

In *Actavis*, the FTC filed suit against a brand manufacturer, Solvay Pharmaceuticals, and generic competitors Actavis and Paddock for entering into "reverse payment" settlement agreements after the brand sued the generics for patent infringement. 133 S. Ct. at 2224–25. Pursuant to those settlements, the generics agreed not to bring their generic products to market for a number of years and further agreed to promote the brand drug to doctors in exchange for a "reverse payment"—that is, a payment from the patentee brand to the alleged patent infringers—of millions of dollars. *Id.* at 2225. The FTC claimed that these suits violated § 5 of the Federal Trade Commission Act 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

[9] The parties do not address the extent to which the state statutes differ from the federal antitrust laws and the standards announced in *Actavis*. Although these potential differences are not raised in Defendants' motion, they may provide an additional basis for dismissal. *See In re Cipro Cases I & II*, 61 Cal. 4th 116, 141 (2015) (noting that *Actavis* is not dispositive of reverse payment claim under California statute). *See also In re Aggrenox Antitrust Litig.*, __ F. Supp. 3d. __, 2015 WL 1311352, at *24 (D. Conn. Mar. 23, 2015) (dismissing indirect purchaser claims where plaintiffs "attempt[ed] to build a Frankensteinian equivalent of *Actavis*" to reach conduct for which plaintiffs could not attack under federal law because of *Illinois Brick*'s prohibition on indirect purchaser suits).

monopoly profits. *Id.* The district court dismissed the suit and the Eleventh Circuit affirmed, 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 2227 (quoting *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)). At that time, this "scope of the patent" test was also employed in other Circuits, including this one. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) *abrogated by Actavis*, 133 S. Ct. 2223. *See also Actavis*, 133 S. Ct. at 2238–39 (Roberts, C.J., dissenting).

In reversing the Eleventh Circuit, the Supreme Court rejected the scope of the patent test, concluding that a reverse payment may sometimes result in anticompetitive harm when a patent holder seeks to "exclude products or processes that do not actually infringe" the patent by paying the alleged generic manufacturer to stay out of the patent holder's market. *See Actavis*, 133 S. Ct. at 2231, 2233. "[R]ather than measur[ing] the length or amount of a restriction solely against the length of the patent's term or its earning potential," the Court instructed, the antitrust question is answered "by considering 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 2231.

The Court based this conclusion on five considerations. First, it noted that a reverse payment has the "potential for genuine adverse effects on competition" because in effect, it amounts to the patentee's purchase of the exclusive right to sell its product—a right that it claims to have under the patent but would lose if the patent was found to be invalid or not infringed. *Id.* at 2234 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460–61 (2009)). Second, it recognized that "these anticompetitive consequences will at least sometimes prove unjustified." *Id.* at 2235–36. Although there may be offsetting, or even pro-competitive justifications for the

settlement, the Court stated that this consideration was insufficient to "justify dismissing [plaintiff's] complaint" because defendants will have the opportunity to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 2236. Third, the Court noted that "where a reverse payment threatens to work unjustified anticompetitive harm," the patentee likely possesses the market power to follow through on that threat. *Id.* Fourth, the Court instructed that it will typically not be necessary "to litigate patent validity" in order to answer the antitrust inquiry because the existence of an "unexplained large reverse payment" suggests that the patentee has "serious doubts about the patent's survival." *Id.* That, "in turn, suggests that the payment's objective is to maintain supracompetitive prices," and that the settlement is unlawful. *Id.* at 2236–37.

Notwithstanding the Court's prohibition on large, unjustified reverse payments, it nonetheless made clear that a patentee and purported infringer may still lawfully settle their suit by other means. It observed, for instance, that they 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.* at 2237. This safe harbor has direct relevance in this case, as discussed further below.

Pursuant to *Actavis*, to trigger antitrust concern, the settlement term at issue must be (1) a "payment" that is (2) made in "reverse"—that is, from the patent holder to the alleged infringer—and is (3) "large," and (4) "unexplained." *See id.* at 2237. Because the "existence and degree of any anticompetitive effects" may vary depending on the particular settlement and the relevant industry, reverse payments are not presumptively unlawful. *Id.* Plaintiffs must therefore prove their case under the rule of reason analysis applied to other types of antitrust claims. *Id.*

In this Circuit, the rule of reason analysis proceeds in three steps:

> First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to [the] defendant to offer evidence that its conduct had pro-competitive effects. If [the] defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104 (2d Cir. 2010), *as corrected* (June 17, 2010) (internal citations and quotations omitted).

A. Alleged Unlawful Reverse Payments

In accordance with the principles stated above, the Court begins its inquiry by assessing whether Plaintiffs have plausibly pleaded a reverse payment with anticompetitive effect. With the exception of Takeda's settlement with Teva,[10] the parties do not dispute that the settlement terms between Takeda and the generics mainly flowed from the patentee to the alleged infringers and were thus "reverse."[11] Defendants argue instead that the settlement terms are not "payments" because, unlike the settlements in *Actavis*, the agreements here provided only early entry licenses to the generic manufacturers. Def. Joint Mem. at 14. They further argue that the "acceleration clauses" in the settlements do not constitute unlawful reverse payments because, if triggered, the clauses allowed generic competition even earlier than otherwise provided for in the agreements. *Id.* at 19. Finally, they contend that even if the licenses may be characterized as "payments," Plaintiffs have failed to plausibly allege that they were "large" or "unexplained" as required by *Actavis*. *Id.* at 28.

For the reasons that follow, the Court agrees that dismissal of these claims is appropriate.

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[10] This settlement is addressed separately below, *infra* p. 29.

[11] Both Ranbaxy and Teva's agreements, however, did contain optional supply provisions that allowed them to purchase drug product from Takeda. Def. Ex. 1, Ranbaxy Agreement at 10; Ex. 5, Teva Agreement at 17.

1. Non-Cash Settlements Under *Actavis*

The settlements in this case do not involve cash payments like the one in *Actavis* and thus require the Court to determine whether they fall within the case's purview. The *Actavis* Court held that a monetary payment from a brand patentee to a generic may potentially violate antitrust principles, and is thus subject to scrutiny under the rule of reason. It is the payment made to the infringer "for staying out of the market" that is of concern because it safeguards the patentee's monopoly returns, even if it splits them between the patentee and the generic challenger. 133 S. Ct. at 2234–35.

The Court in *Actavis* expressly provided, however, that settlements without reverse payments, such as those that permit a generic manufacturer to enter the patentee's market prior to the patent's expiration, remained lawful. *Id.* at 2237. The Government has echoed this position. In the reply brief filed in *Actavis*, the FTC noted that "the parties to paragraph IV litigation have broad freedom to settle by agreeing to a compromise date of generic entry." Pet'r Reply Br., *FTC v. Actavis*, No. 12-CV-416, 2013 WL 1099171, at *8–9 (Mar. 18, 2013). At oral argument, the Deputy Solicitor General reiterated that position: "the kind of settlement that we would regard as legitimate [is] where the parties simply agree to a compromise date of generic entry, then the parties would certainly take into account their own assessment of what would likely happen at the end of the suit." Tr. of Oral Argument at 10, *FTC v. Actavis*, No. 12-CV-416.

Unsurprisingly, many settlement agreements include terms that cannot easily be categorized as either an illegal reverse payment or a legal early-entry settlement—that is, they do not include a cash payment, but they contain more consideration than merely a compromise entry date. As a preliminary matter, because *Actavis* did not explicitly address whether its holding was limited to cash payments, a number of district courts have reached differing conclusions as to

whether a non-cash settlement may ever constitute an unlawful "payment." This Court shares the majority view that *Actavis*'s holding is not limited to payments made in cash. *See, e.g., In re Aggrenox Antitrust Litig.*, __F. Supp. 3d__, 2015 WL 1311352, at *11 (D. Conn. Mar. 23, 2015); *United Food and Comm. Workers Local 1776 & Partic. Emp'rs Health and Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 382 (D. Mass. 2013). *But see In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180 (D.R.I. 2014) (holding that only cash payments fell within ambit of *Actavis*, but noting reservations with that approach); *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D.N.J. 2014), *rev'd, King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015) (reversing lower court's finding that only cash payments stated an *Actavis* claim). This view is consistent with traditional understandings of the term "payment," which is defined in Black's Law Dictionary as the "[p]erformance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full discharge of the obligation." (10th ed. 2014) (emphasis added); *see also Oxford English Dictionary* (3d ed. 2005).

Like several other courts that have considered the question, however, the Court also concludes that not *all* non-cash settlement terms fall within the purview of *Actavis*; rather, in order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term, at least to the extent of determining whether it is "large" and "unjustified." *See Teikoku Pharma*, 74 F. Supp. 3d at 1069–70; *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *21. Contrary to Plaintiffs' contention, this requirement does not require precise calculations or otherwise heighten a plaintiff's pleading burden, but is consistent with the limiting principles articulated in

Actavis for determining whether a reverse payment is subject to antitrust scrutiny. *See* 133 S. Ct at 2237. Indeed, the Supreme Court identified some of the attributes of the payment that should be analyzed, namely, "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.*

In the Court's view, a reading of *Actavis* that would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment would ignore the limiting principles set forth in the decision, and subject virtually *any* settlement to antitrust scrutiny—a result the Court could not have intended. *See Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is . . . classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements.").

a. Takeda's Settlement Agreements with Mylan, Ranbaxy, and Actavis

Applying these principles, the settlement agreements in this case do not provide a basis for a claim under *Actavis*, despite Plaintiffs' creative pleading. Pursuant to the essential terms of the settlement agreements with Mylan, Ranbaxy, and Actavis, Takeda licensed the Generic Defendants to enter the market on August 17, 2012.[12] This date fell approximately 20 months after the 777 patent expired in January 2011, and approximately four years before the 584 and 404 patents expired in June 2016. Moreover, in the event that any other generics received approval to

[12] As described above, Teva was permitted to enter the ACTOS market as Takeda's authorized generic on the same date.

market generic ACTOS prior to that date, each of the settlement agreements contained an acceleration clause which permitted them to immediately enter the market, despite the date fixed in the agreement.

At their core, the settlements at issue simply granted the Generic Defendants a compromise date of generic entry—the very type of settlement sanctioned by the *Actavis* Court. Indeed, the *Actavis* Court expressly provided that a "settlement on terms permitting the patent challenger to enter the market before the patent expires would . . . bring about competition . . . to the consumer's benefit." 133 S. Ct. at 2234. Accordingly, courts have distinguished settlement terms similar to those found in the agreements here from the types of provisions that trigger antitrust scrutiny. *See, e.g., FTC v. AbbVie*, __ F. Supp. 3d __, 2015 WL 2114380 (E.D. Pa. May 6, 2015) (holding that early-entry license does not run afoul of *Actavis* and is procompetitive), *recons. denied*, 2015 WL 5025438 (Aug. 25, 2015); *In re Niaspan*, 42 F. Supp. 3d at 751–52 (distinguishing early-entry license settlements from other forms of consideration).

Plaintiffs do not dispute that a mere early-entry license is insufficient to trigger antitrust scrutiny. They argue, rather, that the settlement agreements in this case were made unlawful because the acceleration clauses discouraged generic competition, and in the case of Ranbaxy and Actavis, the settlements included unlawful compensation in the form of early-entry licenses for generic ACTO*plus*. Pl. Opp. at 16. These arguments fail.

(i) "Acceleration Clauses"

First, as to the acceleration clauses, Plaintiffs have failed to set forth any plausible basis for viewing them as anticompetitive. These clauses, which were present in slightly different forms in each of the Generic Defendants' agreements, allowed entry before August 17, 2012 if another generic came to market first. *See* Def. Ex. 1, § 3.1(b), (c); Ex. 2 § 3.1 (b), (c), (d); Ex. 4 § 3.1 (b),

(c), (d). The rationale behind these provisions is clear. Because the licensing agreements were explicitly non-exclusive, the possibility remained that another generic competitor could pursue ANDA approval and attempt to enter the market before the entry date fixed by the settlement agreements. The acceleration clauses ensured that if a generic or authorized generic began marketing its product before that date, the licensed generic could also enter without further delay. The practical effect of the acceleration clauses was thus to increase competition in the event that other generics entered the market earlier than contemplated by the agreement. If no other generic entered before the licensed entry date, the effect would be neutral. As applied to the facts as alleged in this case, the triggering of the acceleration clause in any of the Generic Defendants' settlement agreements with Takeda would result in four or more generics entering the market, instead of three—an indisputably procompetitive effect. If the clauses were not triggered, the compromise entry date of August 17, 2012 remained in effect and the Generic Defendants retained the 180 days of generic market exclusivity they would have received as first-filers under the Hatch-Waxman Act.

Given this factual context, it is difficult to view the provisions as "payments" from Takeda to the generics to retain monopoly pricing power. As Defendants point out, under the agreements, the Generic Defendants received no compensation from Takeda, but rather, were compensated only through the market when they began selling their generic product. *See* Oral Arg. Tr. at 14. Significantly, Plaintiffs do not allege that the Generic Defendants shared in Takeda's monopoly profits by charging supracompetitive prices when they entered the market. In fact, other than their conclusory allegations that Defendants charged more and Plaintiffs paid more for the drugs than they otherwise would have *before* the date of generic entry, Plaintiffs allege no anticompetitive effects on pricing resulting from the agreements.

Plaintiffs nonetheless argue that the acceleration clauses had the anticompetitive effect of deterring other generics from disputing Takeda's patents—presumably because even if a generic challenger won its suit, it would be deprived of any period of market exclusivity as the licensed Generic Defendants would also enter the market immediately thereafter. *See* Pl. Opp. at 30. While another case may present circumstances in which such a deterrent effect is plausible, Plaintiffs' theory is not borne out here for several reasons. First, Mylan, Actavis, and Ranbaxy were the first-filers as to ACTOS; thus, under the statutory scheme, there is no plausible scenario in which another generic would have been entitled to earlier entry. Although Plaintiffs argue that another generic could have entered earlier by relying solely on a Section viii Statement, that avenue was foreclosed by the FDA's Citizen's Petition decision, which was issued on the same day the settlement agreements took effect. Secondly, after Takeda settled with the Generic Defendants, other generics continued to pursue litigation regarding ACTOS; Teva, for instance, continued to litigate its case for seven months.

But even if the Court were to credit Plaintiffs' speculation as to how other generics would have acted if not for the acceleration clauses, it remains unpersuaded that this kind of settlement term is made unlawful by *Actavis*. An acceleration clause by its plain terms merely affects the date of entry into the market—a date that can be lawfully agreed upon by the parties settling a patent infringement suit. Indeed, Plaintiffs concede that acceleration clauses may be "procompetitive under some circumstances." Pl. Opp. at 34. The mere possibility that the absence of an acceleration clause may result in more diverse generic competition is insufficient for Plaintiffs to plausibly state a reverse payment claim here. *Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize

competition. *See Smithkline Beecham Corp.*, 791 F.3d at 409 ("*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible.")

As Plaintiffs acknowledged at oral argument, no other court has found an acceleration clause to constitute a reverse payment. Oral Arg. Tr. at 98. Without any legal authority or factual basis for doing so in this case, the Court declines to expand *Actavis*'s holding in this manner.[13]

Finally, to the extent Plaintiffs attempt to assert a new theory of antitrust liability in the Hatch-Waxman context, *see* Pl. Opp. at 33–34 (arguing that even if the clauses are not "payments," they are illegal), it is not supported by the allegations in the CAC, which repeatedly and emphatically refer to the provisions as unlawful "payments."

(ii) ACTO*plus* Licenses for Ranbaxy and Actavis

Plaintiffs' arguments regarding the so-called "sweet heart deals" given to Ranbaxy and Actavis for generic ACTO*plus* licenses similarly fail to persuade the Court that the settlements contained unlawful reverse payments. Under those provisions in their respective agreements, Takeda granted Ranbaxy and Actavis licenses to market generic ACTO*plus* as of the earlier of June 15, 2015, or 180 days after the first-filing generic (Mylan) entered the market. Def. Ex. 1 § 3.2; Def. Ex. 4 § 3.2. Plaintiffs argue that these licenses constituted illegal payments because neither Ranbaxy nor Actavis had filed an ANDA for ACTO*plus* and they could not have obtained the licenses as a result of the pending ACTOS litigation with Takeda. Pl. Opp. at 35.

Although ACTOS and ACTO*plus* were different drug products, they are closely related; ACTO*plus* simply combined the ACTOS drug with metformin—a patent-protected combination therapy approved by the FDA as a method of use for ACTOS. Both drugs are covered by the 584

[13] In fact, acceleration clauses were pleaded as an alleged "payment" in *In re Loestrin*, but the Court summarily rejected plaintiffs' theory. *See* 45 F. Supp. 3d at 191 (holding that *Actavis* did not apply to non-cash settlement terms).

and other method of use patents that Takeda accused Actavis and Ranbaxy of infringing in the ACTOS litigation under an inducement theory. *See* CAC ¶ 109.

As to Plaintiffs' argument that Ranbaxy and Actavis could not have obtained this relief in the ACTOS patent litigation, *Actavis* does not provide a legal basis for restricting negotiated settlement terms where they do not restrain competition. Plaintiffs contend that the FTC has asserted that settlements granting licenses for other drugs are anticompetitive. *See* Pl. May 19, 2014 Letter at 1. To the contrary, in another reverse payment case, the FTC posited that *Actavis* only precludes these types of settlements if the consideration could not have been obtained in the litigation *and* "the parties [are] sharing monopoly profits by avoiding competition." Pl. May 19, 2015 Letter, Ex. A at 20. Plaintiffs have not plausibly alleged that the parties charged monopoly prices or shared monopoly profits here.[14]

The prospective effect of the ACTO*plus* licenses on competition was no different from that of the ACTOS licenses discussed above. Like the ACTOS licenses, the ACTO*plus* licenses merely allowed Actavis and Ranbaxy to enter the market earlier than they otherwise would have been permitted to do. The licenses were not exclusive and, because they would only become effective 180 days after Mylan entered the market, they did not give Ranbaxy and Actavis any competitive advantage over other generic ACTO*plus* competitors. Finally, as with the ACTOS licenses, any benefits that Actavis and Ranbaxy received under the agreements were benefits shared by consumers.

Finally, Plaintiffs' speculation that the ACTO*plus* licenses for Ranbaxy and Actavis caused them to agree to a later date of entry in the ACTOS market than they otherwise would have does not alter the Court's conclusion. Pl. Opp. at 16. Both the early-entry ACTOS and ACTO*plus*

[14] At least one other court has rejected a reverse payment claim based on a similar settlement term—licenses for entry in foreign markets for another drug manufactured by the brand. *See In re Lipitor*, 46 F. Supp. 3d at 546.

licenses were permissible settlement terms under *Actavis*, and the simultaneous grant of both does not render either license unlawful. *See AbbVie*, 2015 WL 2114380, at *7 (finding simultaneous agreements between brand and generic regarding different drugs lawful because each agreement, by itself, was procompetitive).

b. Takeda's Licensed Generic Agreement With Teva

Pursuant to its settlement with Teva, Takeda granted Teva a license to enter the ACTOS market as an authorized generic on August 17, 2012, or whenever another generic came to market, and with its own generic product 180 days later. Def. Ex. 5, Teva Agreement §§ 3.1, 3.3. In addition, Teva was granted a license to enter the ACTO*plus* market as Takeda's Authorized Generic on the earlier of December 14, 2012 or when another generic came to market, and with its own product 180 days later. *Id.* §§ 3.4, 3.6. In other words, under the agreements, Teva—which was not a first-filer for either ACTOS or ACTO*plus*—was permitted to enter both markets as an Authorized Generic at the same time as the first-filer Generic Defendants. Finally, Teva was permitted to enter the market with its own product 180 days later, reflecting the same period of exclusivity to which the first-filers would have been entitled had they not settled their litigation with Takeda.

Plaintiffs argue that these settlement terms were anticompetitive because they prevented Teva from entering the market even earlier. Specifically, they posit that Teva had a "substantial likelihood, if not near certainty" of entering the ACTOS market immediately after the 777 patent expired in January 2011, assuming certain events occurred: (1) Teva proceeded to trial against Takeda in June 2010, (2) at trial, Teva invalidated the 584 and 404 patents as to ACTOS and the Orange Book listings for ACTOS were changed, (3) Teva obtained final FDA approval of its ACTOS ANDA with Section viii Statements, including appropriate carve out labels, as to the 584

and 404 patents prior to January 17, 2011, and (4) Teva entered the market immediately after its ANDA was approved. Pl. Opp. at 36–37.

Setting aside the series of inferences the Court must make in order to reach this conclusion, the main flaw with Plaintiffs' argument is that it side-steps the relevant *Actavis* inquiry: was there a large, unexplained reverse payment from Takeda to Teva to settle the litigation? The Teva agreement, like the Generic Defendants' agreements, merely fixed early-entry dates for Teva to enter the ACTOS and ACTO*plus* markets. The only "payments" provided for by the settlement consisted of 75 percent royalty payments from Teva *to* Takeda (*i.e.*, *not* reverse) for marketing its drugs as an authorized generic manufacturer. Def. Ex. 5, Ex. B at 3. As discussed above, this type of early entry date settlement does not trigger antitrust scrutiny under *Actavis*. The possibility of even earlier entry than that contemplated by the settlement agreement does not transform the settlement into an unlawful one.

The particular terms of the licenses also do not change the Court's conclusion. Plaintiffs argue that the Teva settlement was made unlawful by the inclusion of acceleration clauses and "non-compete pledges." Pl. Opp. at 39. The acceleration clauses functioned similarly to those in the other agreements—in the event that another authorized generic or non-first-filer generic entered the market first, Teva was permitted to compete immediately, rather than wait for the date fixed in the agreement. *See* Def. Ex. 5 §§ 3.1, 3.3, 3.4, 3.6. As previously discussed, these clauses are not "payments" under *Actavis*.

Contrary to what Plaintiffs allege, the Teva agreements do not contain so-called "non-compete pledges." Plaintiffs cast these provisions as "no authorized generic" promises, but this misconstrues the meaning of the term. As Plaintiffs acknowledged at oral argument, neither Takeda nor any other brand manufacturer is obligated as a matter of law to license an authorized

generic. Oral Arg. At 33. In any event, Takeda *did* opt to license an authorized generic; it licensed Teva to enter the ACTOS and ACTO*plus* markets as its Authorized Generic during the first 180 days of generic marketing for each drug. It is beyond dispute that doing so increased generic competition during those periods. Furthermore, the settlement did not preclude Takeda from authorizing any other generic; it expressly reserved Takeda's right to grant licenses for authorized generic ACTOS and ACTO*plus* products to the first ANDA filers for each drug during the first 180 days of generic marketing, and to any other manufacturer at the conclusion of that period. *See* Ex. 5, §§ 3.2, 3.5.

These circumstances stand in stark contrast to a true "no authorized generic" pledge, where the brand name settles exclusively with one generic and agrees not to market its own generic drug during the first 180 days of marketing—thereby limiting competition to just one generic drug. *See, e.g., Smithkline Beecham, Corp.*, 791 F.3d at 407–09 (reversing district court and holding that agreement pursuant to which brand manufacturer agreed not to introduce an authorized generic during the first 180 days of generic marketing was subject to rule of reason scrutiny under *Actavis*); *Teikoku Pharma*, 74 F. Supp. 3d at 1072 (concluding that plaintiffs plausibly alleged reverse payment based on no-authorized generic agreement in which the brand manufacturer agreed not to release their authorized generic until seven and one-half months after settling generic manufacturer began selling its version); *In re Niaspan*, 42 F. Supp. 3d 735, 744, 751–52 (brand manufacturer agreed not to launch any authorized generic until 180 days after settling generic launched its product).[15] The Court agrees with Plaintiffs that such arrangements trigger antitrust

[15] The agreements in *Teikoku Pharma* and *In re Niaspan* included additional payment-like terms. In *Teikoku Pharma,* the settlement included a supply agreement under which the patentee supplied the infringer generic with product worth $12 million dollars once a month for eight months. 74 F. Supp. 3d at 1070. The settlement terms in *In re Niaspan* included a co-promotion agreement under which the brand paid the generic a royalty on all sales of the drug at issue and another drug produced by the brand in return for product promotion, as well as a manufacturing agreement that included a lump sum and quarterly payments from the brand to the generic in exchange for the generic agreeing to act as a back-up supplier for the brand. 42 F. Supp. 3d at 744.

scrutiny due to their potential anticompetitive effect. *See Smithkline Beecham Corp.*, 791 F.3d at 407–09; *see also* "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," Federal Trade Commission, August 2011 Report.

Takeda, however, did not make a similar promise; indeed, each of the settlement agreements at issue in this case, including that with Teva, preserved Takeda's right to authorize generic forms of both ACTOS and ACTO*plus* from the first filers. That Takeda opted to license one rather than multiple authorized generics during a period in which the other generics were guaranteed entry—three others manufacturers with respect to ACTOS and one other with respect to ACTO*plus*—does not render Takeda's agreement with Teva illegal. Plaintiffs cite no legal authority to the contrary.

c. Value of the Settlements

For the foregoing reasons, the Court concludes that the settlements at issue were not "reverse payments" within the meaning of *Actavis*. Even if the Court were to view the licensing terms as reverse payments, however, Plaintiffs' claims fail for the additional reason that they do not plausibly allege that the payments were "large" and "unjustified." Although the Supreme Court did not define "large" in *Actavis*, it instructed that the payment be compared to the payor's future litigation costs as a measure of scale. 133 S. Ct. at 2237. As to whether the payment was "unjustified," the Court explained that a payment is justified if it "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services." *Id.* at 2236. In such circumstances, "there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.*

As explained above, to meet their pleading burden as to whether the payments were "large" and "unjustified," Plaintiffs must plausibly allege a factual basis for the Court to reasonably

estimate the value of the settlement terms. For instance, Plaintiffs cite a recent decision from the Eastern District of Pennsylvania in which the court concluded that payments were sufficiently large to defeat summary judgment. There, the record contained both dollar amounts paid to the generics under settlement agreements as well as the amounts saved in litigation costs, enabling the court to compare the two. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, __F. Supp. 3d__, 2015 WL 356913, at *3–4, 13–14 (E.D. Pa. Jan. 28, 2015).[16] Similarly, in *Teikoku Pharma,* the Northern District of California court found allegations that calculated the difference in projected revenues under an agreement prohibiting an authorized generic, and projected revenues with an authorized generic on the market, to be sufficient to state a claim for relief. 74 F. Supp. 3d at 1071, (estimating that brand's projected revenues were $170,000,000 higher with the agreement than without it).

By contrast, while Plaintiffs allege that the licensing terms in the settlements were of "substantial value" and worth "tens" and "hundreds of millions" of dollars, they do not explain the basis for those assertions, or offer any method of calculating the value of the licensing terms. *See, e.g.* CAC ¶ 114, 134, 156, 159–60, 162. Instead, Plaintiffs argue that the actual value of the payments is "irrelevant" because they have alleged that the payments were "sufficiently large." Pl. Opp. at 43. The Court disagrees. *Twombly* requires more than mere "labels and conclusions" to state a claim for relief. 550 U.S. at 555. Although Plaintiffs need not provide precise calculations at the pleading stage, here, they do not even attempt to provide a factual basis for the "tens" and "hundreds of millions" of dollars allegedly paid by Takeda. The bare allegations in the CAC are thus insufficient for the Court to make a reasonable estimate of the settlements' value

[16] The settlements in *King Drug* included actual cash payments as well as supply and manufacturing provisions. 2015 WL 356913, at *3–5.

and determine whether they constituted large and unjustified payments. *See In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *21 (discussing no-authorized generic clause and concluding that to state a claim, plaintiffs must provide "some reliable foundation to show that a reverse payment agreement was actually entered and present specific facts showing how the alleged non-monetary payment was calculated").[17]

Moreover, Plaintiffs have failed to plausibly allege any other factual basis for the Court to evaluate the settlements' unlawful anticompetitive effect. They have not, for instance, alleged that any particular generic manufacturers were deterred from earlier entry, or alleged any specific effect on price. In these circumstances, crediting Plaintiffs' unsupported assertions that the settlements were unlawful "payments" would suggest that any and all settlements between a brand and a manufacturer are potentially unlawful—a result that the *Actavis* Court was unlikely to have intended.

B. Rule of Reason Analysis

In sum, although the Court recognizes that some settlements with non-cash settlement terms may provide a basis for an *Actavis* reverse payment claim, the settlement agreements in this case do not. Plaintiffs have thus failed to meet their initial burden under the rule of reason of alleging cognizable anticompetitive conduct. Accordingly, the Court need not proceed further with the rule of reason analysis; Counts 3–6 and Counts 8 and 9 are dismissed.

[17] Another court in this Circuit has suggested that generalized allegations may suffice on this issue. *See In re Aggrenox*, 2015 WL 1311352, at *13 (rejecting defendants' argument that allegations of the settlement's value were not sufficiently specific, noting that "precise and particularized estimates of fair value and anticipated litigation costs" may require discovery). In contrast to the facts here, however, the allegations in *In re Aggrenox* specified the amounts of upfront cash payments and royalties paid under the agreements. *Id.* at *12.

II. Monopolization Claims against Takeda

In Count 1, Plaintiffs allege that Takeda monopolized the market for ACTOS by submitting "improper" patent information regarding the 584 and 404 patents and entering into unlawful settlement agreements with the Generic Defendants that had the effect of creating a "bottleneck" on competition. CAC ¶¶ 230–238. In Count 2, Plaintiffs allege that Takeda attempted to monopolize the ACTOS market, although it alleges no particular anticompetitive conduct in which Takeda engaged to do so. *Id.* ¶¶ 239–246.

As with their other claims, Plaintiffs do not set forth the requirements for a monopolization claim under the numerous state laws cited in the CAC, nor do they plead any state-specific factual allegations. Assuming, as the parties do, that those statutes accord with the federal standard, Plaintiffs have not met their pleading burden. Pursuant to Section 2 of the Sherman Act, it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 2. Plaintiffs asserting a monopolization claim must allege that (1) the purported monopolizer possesses monopoly power in the relevant market, as well as (2) the intent to monopolize—*i.e.* "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." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP,* 540 U.S. 398, 407 (2004)). To protect the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct, that is, "conduct without a legitimate business purpose that makes sense only because it eliminates competition." *Id.* (quoting *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 124 (2d Cir. 2007)). In addition, plaintiffs also "must allege facts sufficient to prove that [they] suffered

'antitrust injury,'" from the defendants' conduct. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 219 (quoting *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977)). This injury must be an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Id.*

The first element of a monopolization claim—market power—is not in dispute. As to anticompetitive conduct, Plaintiffs specifically allege that Takeda acted anticompetitively by (1) listing false patent information for ACTOS in the Orange Book, and (2) entering unlawful settlement agreements. Takeda responds that it was required to list the patents in the fashion it did and did not provide any patent information in bad faith, and that Plaintiffs have not plausibly alleged that the Orange Book listings caused antitrust injury. Takeda Mem. at 1–2.

A. Listing of Patent Information for ACTOS in the Orange Book

Plaintiffs allege that Takeda acted anticompetitively by listing the 584 and 404 patents in the Orange Book as "drug product patents" because those patents did "not claim the ACTOS drug product"; in other words, they assert that the 584 and 404 patents correspond to different drug compositions than that in ACTOS. Pl. Opp. at 47; CAC ¶¶ 92–93. According to Plaintiffs, the listing of these patents caused generic ANDA filers to file Paragraph IV Certifications instead of Section viii Statements as to those patents, triggering patent infringement litigation by Takeda and a 30 month delay in FDA approval of the generic ANDAs, and thereby delaying generic entry into the ACTOS market. Plaintiffs contend that this patent litigation and delay in FDA approval were improper because the drug component claims of the 584 and 404 patents would not have been infringed by the applications. Pl. Opp. at 49.

To support this theory, Plaintiffs rely on the alleged invalidity of the 584 and 404 drug component claims as to the ACTOs drug. *Actavis* instructs, however, that litigating the validity of

the patent is "normally not necessary" to "answer the antitrust question"; instead, courts may look to the value of the settlement offered by the brand as a proxy for the strength of the patent. 133 S. Ct. at 2236. Of course, in some cases, the invalidity of the patent will be readily established and the Court need not rest its analysis on the settlement value. For example, following a bench trial in which the patent at issue was held to be invalid and procured by fraud, the court in *FTC v. Cephalon, Inc.* concluded that the brand name manufacturer was collaterally estopped from asserting "the strength of its patent, or litigation uncertainty and business risk" as defenses against a reverse payment antitrust claim by the FTC. 36 F. Supp. 3d 527, 537 (E.D. Pa. 2014). In such a case, the brand manufacturer is properly estopped from relying on the validity of the patent as a defense to an antitrust claim because it is well established that "one who acted fraudulently in obtaining a patent necessarily knows its patent is unenforceable." Phillip E. Areeda and Herbert Hovenkamp, *Antitrust Law* ¶ 706a2.

The facts alleged here, however, do not provide a basis for litigating the 584 and 404 patents to "answer the antitrust question," *Actavis*, 133 S. Ct. at 2236, because even assuming the allegations to be true, Plaintiffs have not plausibly alleged an antitrust injury resulting from Takeda's conduct. At the time of the settlements at issue, no patent listed for ACTOS, including the 584 and 404 patents, had been found invalid or not infringed by a generic ANDA; the only relevant ruling on the ACTOS patents to date was Judge Cote's decision that the 777 patent *was* valid and had been infringed by Mylan. *See Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341, 344 (S.D.N.Y. 2006) *judgment entered sub nom., Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, 2006 WL 618424 (S.D.N.Y. Mar. 13, 2006) *and aff'd sub nom., Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). Indeed, Plaintiffs do not dispute that the 777 patent was properly listed in the Orange Book for Takeda's ACTOS NDA.

Furthermore, as Takeda argues in its motion papers, it was required under the Hatch-Waxman Act to list any patent which claimed *either* the ACTOS drug or a method of using the drug. Takeda Mem. at 10 (citing 21 U.S.C. § 355(b)(1)). Although Plaintiffs dispute that the 584 and 404 patents claimed the ACTOS drug product, they do not dispute that the patents claimed methods of using ACTOS in conjunction with an insulin secretion enhancer (sulfonylurea) or biguanide (metformin). There is thus also no dispute that the 584 and 404 patents were properly listed in the Orange Book by Takeda as claiming methods of using ACTOS.[18]

For this reason, Plaintiffs have not sufficiently alleged an antitrust injury resulting from Takeda listing the 584 and 404 patents in the Orange Book. Plaintiffs summarily allege that had Takeda submitted correct patent information, "no ANDA filed would (or could) have submitted a Paragraph IV Certification for ACTOS with respect to the 584 and 404 patents," and would have submitted only Section viii Statements—averting the 30 month delay in FDA approval. CAC ¶ 102. As explained above, however, every ANDA submitted must "despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent"—including method of use patents. 21 C.F.R. § 314.53(f). Accordingly, even if the 584 and 404 patents were described only as claiming methods of using ACTOS, each ANDA filer would have been required to submit an appropriate certification for those patents, *i.e.* either: (1) a Paragraph IV certification if they intended to market the drug for the same use, or (2) a request for FDA approval for a "carve out" label that did not overlap with the patented methods of use. *See*

[18] Takeda further argues that Plaintiffs' argument fails because the regulatory scheme requires only that the brand manufacturer list "patents" in the Orange Book, and does not provide for a "claim-by-claim" listing system for patents with multiple claims. Takeda Mem. at 15 ("The number of claims contained within a particular patent does not affect the ability of the patent to be listed as long as there is at least one claim that meets the two required elements." (citing 68 Fed. Reg. 36,676, 36,685 (June 18, 2003)). The Court need not engage in a textual analysis of the regulations, however, because as discussed below, even assuming the listing of the 584 and 404 patents in the Orange Book was, at least in part, inaccurate, Plaintiffs have not plausibly alleged an antitrust injury resulting from that conduct.

Caraco Pharm. Labs., 132 S. Ct. at 1677. Plaintiffs' conclusory allegations that the generic manufacturers nonetheless could have filed only Section viii Statements are thus inconsistent with the applicable statutory requirements and do not raise Plaintiffs' right to relief beyond a speculative level.

In any event, even crediting Plaintiffs' speculation that no generic would have filed a Paragraph IV Certification if not for the inaccurate Orange Book information provided by Takeda, Plaintiffs have not plausibly alleged that Takeda's conduct unlawfully delayed generic entry. After the Generic Defendants filed ANDAs with Paragraph IV Certifications as to the 584 and 404 patents, Takeda filed patent infringement actions against them on October 17, 2003. Those actions triggered the 30-month waiting period for FDA approval of the ANDAs, precluding any generic entry in the ACTOS market until April 17, 2006. The delay of generic entry until April 17, 2006 is thus plausibly attributed to Takeda's alleged conduct. Plaintiffs cannot allege an antitrust injury resulting from that delay, however, because there is no dispute that generic entry was lawfully precluded until January 17, 2011, the date that the 777 patent expired. In other words, regardless of any delay caused by Takeda's Orange Book listing for ACTOS, neither the Generic Defendants nor any other generic manufacturer could have entered the ACTOS market prior to January 17, 2011—nearly five years after the 30 month waiting period for FDA approval ended. Because there is no dispute that generic entry was lawfully barred until that date, Plaintiffs cannot plausibly allege an actionable antitrust injury resulting from Takeda's alleged Orange Book violation.[19]

B. Settlement Agreements

Takeda's grant of licenses to the Generic Defendants and Teva to enter the ACTOS and ACTO*plus* markets also fail to provide a basis for the monopolization claim. By their plain terms,

[19] Plaintiffs' theory that the Orange Book listings served as a "lynchpin" for the settlement agreements, Pl. Opp. at 54, is discussed separately below.

the settlements resulted in additional competition as of an agreed-to entry date, rather than a further concentration of market power in Takeda. In addition, the agreements did not preclude other generic manufacturers from also entering the market. Plaintiffs' attempt to recast the reverse payment claims as stand-alone monopolization claims thus fails.

Viewing the settlements in the context of Plaintiffs' Orange Book allegations does not alter the Court's conclusion. Although Plaintiffs dispute the validity of some of Takeda's patent claims, this is not an example of "sham" infringement litigation by a brand manufacturer. *See Actavis*, 133 S. Ct. at 2236.[20] Plaintiffs acknowledge that Takeda's infringement suits against Defendants included both infringement and inducement claims. *See* CAC ¶¶ 109, 144. Setting aside the drug product claims of the 584 and 404 patents, the Generic Defendants may nonetheless have been found liable for inducing infringement of those patents' method of use claims.

Indeed, Judge Cote denied Actavis' motion to dismiss Takeda's patent infringement lawsuit on this very basis. *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394, 401 (S.D.N.Y. 2004) (finding allegations that Actavis (then Watson) "ha[d] taken and will take acts to induce infringement of [the 584 and 404] patents" sufficient to state a claim for relief). Similarly, in a parallel infringement action against another generic ACTOS manufacturer, Judge Cote denied the generic's motion for judgment on the pleadings, concluding that the Court could not find as a matter of law "that a generic drug manufacturer cannot induce infringement of combination-use patents as a matter of law after the principal patent has expired." *Takeda Pharm. Co. v. Sandoz, Inc.*, No. 07-CV-3844, 2007 WL 2936208, at *5 (S.D.N.Y. Oct. 9, 2007). These

[20] To be considered "sham litigation," a lawsuit must be (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) conceal "an attempt to interfere directly with the business relationships of a competitor." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993).

rulings established that far from constituting a "sham litigation," there was at least a colorable legal basis for Takeda to pursue induced infringement claims against the Generic Defendants and Teva (as well as a basis for the generic manufacturers to pursue settlement), notwithstanding the generics' positions on the 584 and 404 patents' validity. *See Commil USA, LLC v. Cisco Sys. Inc.*, 135 S. Ct. 1920, 1922 (2015) (holding that "[a] defendant's belief regarding patent validity is not a defense to an induced infringement claim").

In sum, Plaintiffs do not plausibly allege that Takeda engaged in anticompetitive conduct to monopolize or attempt to monopolize the ACTOS market. Accordingly, Counts 1 and 2 are dismissed.

III. "Overarching" Conspiracy Claim

In Count 7, Plaintiffs allege that "[t]hrough an overarching anticompetitive scheme, including the Exclusion Payment Agreements . . . Defendants conspired to block and delay the entry into the market of generic ACTOS." CAC ¶ 284. This claim fails as a matter of law.

As with their other antitrust claims, Plaintiffs fail to plead the elements of an overarching conspiracy claim under any of the state laws they list in Count 7. Under federal law, which the parties cite to in their briefs,[21] the "crucial question" in any conspiracy case is "whether the challenged conduct stems from independent decision or from an agreement, tacit or express." *Mayor & City Council of Baltimore, Md. v. Citigroup, Inc.*, 709 F.3d 129, 135 (2d Cir. 2013) (internal quotation omitted); *see also Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012) ("whether [the conspiracy is] horizontal, vertical, or both, proof of joint or concerted action is required; proof of unilateral action does not suffice"). The existence of an agreement is a legal conclusion; a mere conclusory allegation that Defendants agreed to enter into

[21] *See* Def. Joint Mem. at 37; Pl. Opp. at 67. The Court therefore relies on the federal standards set forth pursuant to the Sherman Act, 15 U.S.C. § 1.

unlawful settlements without supporting factual allegations is insufficient to state a claim for relief. *See Mayor & City Council of Baltimore, Md.*, 709 F.3d at 135 (citing *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 319 n.2 (2d Cir. 2010)). Rather, "[a] plaintiff's job at the pleading stage, in order to overcome a motion to dismiss, is to allege enough facts to support the inference that a conspiracy actually existed." *Id.* at 136.

Plaintiffs may do this in one of two ways. First, they may allege direct evidence that defendants entered into an agreement in violation of the antitrust laws. *Id.* (citing *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323–24 (3d Cir. 2010)). Secondly—and more commonly because direct evidence is often unavailable—plaintiffs may present circumstantial facts supporting the inference that a conspiracy existed. *Id.* Such facts may include conscious parallel or interdependent conduct, although parallel conduct alone is generally insufficient to defeat a motion to dismiss. *Id.* (citing *Twombly*, 550 U.S. at 551, 553, 556, which held that allegations of illegal agreements based solely on the parallel actions by competitors failed to state a claim). This is because parallel conduct by competitors may be explained by "rational and competitive business strategy unilaterally prompted by common perceptions of the market," just as reasonably as it may be explained by an unlawful agreement. *Id.* at 137 (quoting *Twombly*, 550 U.S. at 554).

Therefore, when relying on parallel or interdependent conduct as circumstantial evidence, plaintiffs must also allege the existence of other circumstances, typically called "plus factors," that when viewed in conjunction with the conduct, support an inference of an agreement. *Id.* at 136 (citing *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001)). These factors may include a common motive to conspire, evidence establishing that the conduct was against the economic self-interest of the alleged conspirators, and frequent inter-firm communications. *U.S. v. Apple Inc.*, 952 F. Supp. 2d 638, 690 (S.D.N.Y. 2013), *aff'd*, 791 F.3d. 290 (2d Cir. 2015). Moreover, the

parallel actions and "plus factors" alleged must actually support an inference of conspiracy; that is to say, the allegations "must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Twombly*, 550 U.S. at 557. In a particular case, it may be that the "plus factors" support "an equally plausible inference of mere interdependent behavior, *i.e.*, actions taken by market actors who are aware of and anticipate similar actions taken by competitors, but which fall short of a tacit agreement." *Mayor & City Council of Baltimore*, 709 F.3d at 137 (quoting *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 254 (2d Cir. 1987)).

Plaintiffs argue that the settlement agreements in this case are evidence of a "hub-and-spoke" conspiracy to control the ACTOS and ACTO*plus* markets. Pl. Opp. at 66–68. In this type of conspiracy, the "hub" defendant coordinates a series of substantively identical agreements with the "spoke defendants" (usually vertical partners) while ensuring the spoke defendants that the same deal was offered to each. *See In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 685 (S.D.N.Y. 2012). To establish a hub-and-spoke conspiracy, the plaintiff must demonstrate both that there was a horizontal agreement between the spoke defendants, and that each of those defendants was a "knowing participant in that agreement and facilitated the scheme." *Apple*, 952 F. Supp. 2d at 690. Plaintiffs have not, however, plausibly alleged the existence of any overarching illegal agreement—"hub-and-spoke" or otherwise—between Defendants. The allegations in the CAC establish only that the Generic Defendants entered into similar agreements with Takeda and that they were aware of the relevant terms—*i.e.* the date of entry—in the other generics' agreements. At most, these allegations establish parallel or interdependent conduct. As to Teva, Plaintiffs have not plausibly alleged even parallel conduct; rather, the CAC asserts that Teva continued litigating Takeda's patents after the Generic Defendants settled. Moreover, there are

not sufficient "plus factors" alleged to support an inference that any of the Defendants unlawfully agreed to coordinate their settlements to block or delay generic competition.

Plaintiffs have not, for instance, plausibly alleged that the agreements were against Defendants' self-interest "'in the absence of similar behavior by its rivals,'" which would suggest that "each [D]efendant . . . received assurances that all its rivals [would] act similarly." *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2014 WL 2813312, at *11 (E.D. Pa. June 23, 2014) (quoting *Starr*, 592 F.3d at 327). *See also Apple*, 952 F. Supp. 2d at 693 (explaining that but for the collective action that Apple, the "hub" defendant, nurtured, no individual defendant would have succeeded in imposing the anticompetitive arrangement); *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 935 (7th Cir. 2000) (describing how the agreements were financially disadvantageous to the "spoke" defendants). By contrast, the agreements in this case were in accord with the independent interests that each of the Generic Defendants and Teva had in settling their lawsuits and entering the generic market.

Moreover, the settlement agreements reflected each Defendant's respective rights under the Hatch-Waxman statutory scheme: the "first-filers" (Mylan, Actavis, and Ranbaxy for ACTOS, and Mylan for ACTO*plus*) maintained some semblance of their 180 day period of exclusivity, and Teva, which did not have first-filer status, was permitted to enter simultaneously as an authorized generic, and with its own generic product 180 days later. *See* Def. Exs. 1–5. Thus, as the court observed in *King Drug Co. of Florence v. Cephalon, Inc.*, "the settlements seemed to offer the best of both worlds: an end to costly litigation, combined with lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding [generic entry]." 2014 WL 2813312, at *12 (E.D. Pa. June 23, 2014) (rejecting conspiracy claim in reverse payment case where the agreements were economically beneficial). Conversely, there is no factual basis from

which to infer that, on balance, the agreements were against the Defendants' self-interest. Plaintiffs' argument to the contrary requires the Court to assume that Defendants would have fared better had they proceeded to trial, and that assumption is pure speculation.[22]

Similarly, Plaintiffs do not allege that the Generic Defendants communicated with each other in advance of entering the settlements, or that the agreements were negotiated together. Indeed, there are no specific allegations regarding advance planning or coordination between the Generic Defendants, Takeda, and Teva. This again contrasts with the circumstantial evidence alleged in cases in which the court found a conspiracy claim to be sufficiently stated. For example, in the purchaser class action regarding Apple's e-book price-fixing conspiracy with various publishers, the complaint described not only allegations of action against self-interest, but also circumstantial evidence of prior meetings between the publisher defendants, public statements made by Apple's Chief Executive predicting a change in prices, and evidence of meetings held on the same day in which the publishers made identical demands from Amazon. *In re Elec. Books*, 859 F. Supp. 2d at 687–88.

Plaintiffs' allegations of an agreement, on the other hand, lack any factual support and are entirely conclusory. *See, e.g.*, CAC ¶ 140 ("Takeda and its generic coconspirators worked together to neutralize the potential competitor [Teva] and bring it into the conspirators' non-competition pact."); *id.* ¶ 151 ("Mylan, Ranbaxy, and Actavis agreed that Takeda could advise Teva of the existence of the acceleration clauses."). The overall thrust of the CAC further weakens Plaintiffs' argument; rather than describing advance planning and coordinated action by the Defendants, it details the bilateral agreements between Takeda and each of the other Defendants that reflected

[22] See more detailed discussion *infra* pp. 46–48.

their respective entry rights in each market under the statutory scheme. *See* CAC Counts 3–6. The "overarching conspiracy" claim thus lacks sufficient factual support.

Finally, even if Plaintiffs had plausibly alleged an unlawful agreement, the overarching conspiracy claim would nonetheless fail on the second prong as there has been no unreasonable restraint of trade. *See Apple*, 952 F. Supp. 2d at 687–88 (discussing requirements of Sherman Act, which "does not disallow any and all agreements" but only "unreasonable restraints") (internal quotation and citation omitted). To the extent Plaintiffs rely solely on the terms of the settlement agreements between Takeda, the Generic Defendants, and Teva, as discussed above, Plaintiffs have failed to establish that those settlements contained unlawful payments or otherwise illegally restrained the ACTOS or ACTO*plus* markets. Accordingly, Plaintiffs cannot satisfy this prong of their antitrust claim.

Count 7 is thus dismissed.

IV. Causation

In further support of their motion to dismiss the antitrust claims in the CAC, Defendants argue that Plaintiffs' general theory of causation is too speculative to state an antitrust injury resulting from the settlement agreements. Def. Joint Mem. at 33.[23] The Court agrees this provides an additional basis for dismissal.

Plaintiffs do not dispute that causation is an essential element of their antitrust claims. Pl. Opp. at 73. *See also Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 415 n.8 (2d Cir. 2014) ("[L]ack of causation in fact is fatal to the merits of any antitrust claim.") (quoting *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986)). They allege, however, that the

[23] Actavis and Teva additionally assert that Plaintiffs' claims against them fail as a matter of law because their settlements with Takeda could not have caused Plaintiffs' alleged injury. *See* Actavis and Teva Mem. at 2. In light of the Court's conclusion that Plaintiffs have failed to sufficiently allege causation as to all of the Defendants, it need not address this argument.

settlement agreements caused their injuries by requiring them to pay higher than necessary prices for ACTOS from January 17, 2011 and for ACTO*plus* from February 25, 2011—when they claim generic entry could have begun—to August 17, 2012—the date of generic entry set by the settlement agreements. *See* CAC ¶¶ 214–19. Plaintiffs assert that earlier entry could have occurred in "at least the following ways": (1) if Takeda listed the 584 and 404 patents as only method of use patents, no generic would have filed Paragraph IV Certifications, leading to "massive generic entry" on or about January 17, 2011; (2) if Teva won its proposed Orange Book counterclaim against Takeda, it would have entered on or about January 17, 2011; and (3) if Mylan did not accept unlawful "payments," it would have received an earlier entry date. Pl. Opp. at 73.

The Court has addressed, and disposed of, the alleged factual bases asserted for these theories in the context the antitrust claims discussed above. Even setting aside those previously identified issues, however, Plaintiffs' proffered theories of causation fail to state a claim for relief. Pursuant to the first theory, for instance, the Court must assume (i) that the 584 and 404 patents were inaccurately listed in the Orange Book; (ii) that the generics would have avoided filing Paragraph IV Certifications with their ANDAs by obtaining final FDA approval of carve-out labels as to the patents' method of use claims; and (iii) that Takeda would not have pursued litigation based on the Defendants' induced infringement of the method of use claims. This last assumption is particularly vexing because, as discussed above, there is no dispute that Takeda did pursue infringement inducement claims. CAC ¶¶ 109, 144. As to the second theory, the Court must assume (i) that the district court would have permitted Teva to amend its answer to include the Orange Book counterclaim; and (ii) that Teva would have pursued the counterclaim and prevailed at trial. Plaintiffs' third theory fails because as noted above, they have not plausibly alleged that

Takeda offered unlawful payments to Mylan to induce later entry, and the allegation that Mylan would have obtained a better result by not accepting a settlement has no factual basis in the CAC.

In sum, the unsupported speculation underlying each of Plaintiffs' theories is insufficient to plausibly allege causation. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 201–07 (E.D.N.Y. 2003) (holding that various theories of causation regarding the timing of FDA approval and success in underlying patent litigation were too speculative to state a claim for relief). In particular, each of the theories requires the Court to assume that Takeda's patent claims were invalid and the infringement actions against the Defendants would have failed. Such assumptions regarding success at trial are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise. *See id.* at 201–02; *AbbVie*, 2015 WL 2114380, at *8. Because Plaintiffs have failed to do so here, they cannot establish an antitrust injury caused by Defendants' conduct.[24] Plaintiffs' antitrust claims must therefore be dismissed on this basis as well.

V. State Consumer Protection Claims

In Counts 10 and 11, Plaintiffs allege that Defendants violated numerous state consumer protection laws. Specifically, Plaintiffs assert that there was a "gross disparity between the price that Plaintiffs and the Class members paid for the brand product" as compared to the price of "generic products which should have been available." CAC ¶¶ 311–12, 316–17. Plaintiffs do not

[24] Another case may present circumstances where the generic's success in the patent litigation was less speculative. For instance, in *In re Niaspan*, the court held that plaintiffs' theory of causation based on likely success in the underlying patent litigation was sufficient to withstand a motion to dismiss. 42 F. Supp. 3d at 755–57; *see also In re Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 211–12. In contrast to the allegations here, however, the plaintiffs in that case alleged a reverse payment as well as specific facts evincing that the generic was "confident that it would ultimately prevail" in the patent litigation, including that the generic had begun preparing to launch at-risk as soon as it obtained final FDA approval and that stock prices for the brand had dropped as a result. 42 F. Supp. 3d at 756.

identify any specific provisions of the various state laws that were purportedly violated, nor do they plead any particular conduct in violation of those provisions.

As a court in this district observed, "different state consumer protection statutes contain "'not only nuances, but differing standards of proof, procedure, substance, and remedies.'" *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 409 (S.D.N.Y. 2011) (quoting *Tylka v. Gerber Prods. Co.*, 178 F.R.D. 493, 499 (N.D. Ill. 1998)). Plaintiffs fail to account for these differences in the CAC. Indeed, in Counts 10 and 11, Plaintiffs merely restate their antitrust allegations as separate consumer protection claims, providing no distinct factual basis for a violation of consumer protection law. This is insufficient to meet the Rule 8 pleading standard under *Twombly* and *Iqbal*. *See In re Aggrenox*, 2015 WL 1311352, at *23–24 (dismissing state consumer protection claims by indirect purchaser class on same basis).[25]

The Court thus concludes that Plaintiffs have failed to plausibly allege violations of the various state consumer protection statutes listed in the CAC and Counts 10 and 11 are dismissed.

VI. Unjust Enrichment Claims under State Law

Finally, Defendants argue that Plaintiffs have similarly failed to sufficiently allege the unjust enrichment claims in Counts 12 and 13. Def. Joint Mem. at 43. The Court agrees. Plaintiffs generally allege claims for unjust enrichment under the laws of "all states and jurisdictions within the United States, except for Indiana and Ohio." CAC ¶¶ 328, 340. The CAC does not contain any state-specific allegations, even though "unjust enrichment is not a catch-all claim existing within the narrow scope of federal common law," but rather a state-specific remedy. *See In re*

[25] Although the court in *In re Bayer Corp. Combination Aspirin Products Mktg. & Sales Practices Litig.*, a case cited by Plaintiffs in their brief, found "cursory" allegations linking the defendants' conduct to certain state statutes to be sufficient, that complaint contained significantly more specific allegations regarding the consumer protection statutes in the states where the named plaintiffs resided as well as separate conduct that purportedly violated those laws. 701 F. Supp. 2d 356, 378–79 (E.D.N.Y. 2010)).

Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 167 (E.D. Pa. 2009) (citing *Woodward Governor Co. v. Curtiss Wright Flight Sys., Inc.*, 164 F.3d 123, 129–130 (2d Cir. 1999)). *See also Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *27–30 (E.D. Pa. June 10, 2015) (discussing "significant" differences in state unjust enrichment laws in the context of class certification analysis). The Court must therefore defer to the substantive state common law of those states' courts to determine whether relief is available. *See Goldemberg v. Johnson & Johnson Consumer Co.*, 8 F. Supp. 3d 467, 484 (S.D.N.Y. 2014) ("Certainly, if in [the state court] the instant claim for unjust enrichment would be unavailable . . . it must equally be unavailable in the Federal courts."). Plaintiffs have failed to provide the Court with any state-specific basis for making such determination.

Even in more general terms, however, Plaintiffs' claims fall short. "Although the requirements to plead unjust enrichment vary by state, almost all states at minimum require plaintiffs to allege that they conferred a benefit or enrichment upon defendant and that it would be inequitable or unjust for defendant to accept and retain the benefit." *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d at 411 (internal quotations and citation omitted). An unjust enrichment claim may be "autonomous," meaning it provides an independent ground for restitution, or "parasitic," that is, based on a predicate violation. *Id.* at 411–12. Here, although Plaintiffs do not specify which type of claims they assert, Counts 12 and 13 rely on the same conduct underlying the antitrust claims in the CAC; therefore, the unjust enrichment claims may be considered parasitic.[26] However, because no antitrust claim survives, the parasitic unjust enrichment claims must be dismissed as well. *See Kramer v. Pollock-Krasner Found.*, 890 F. Supp. 250, 257

[26] In any event, an autonomous claim would fail here because "autonomous restitution only exists in the absence of a violation of law," and here, the conduct alleged is governed by federal and state antitrust laws. *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d at 412.

(S.D.N.Y. 1995) (dismissing unjust enrichment claim where underlying antitrust claims failed); *In re Aluminum Warehousing Antitrust Litig.*, No. 13-MD-2481 (KBF), 2014 WL 4743425, at *4 (S.D.N.Y. Sept. 15, 2014).[27]

CONCLUSION

Two years after *Actavis*, federal judges continue to grapple with its implications and many questions of first impression remain to be decided. One thing should be clear. While some settlements of patent infringement suits may produce anticompetitive effects yet be cleverly designed to evade antitrust scrutiny, not all settlements are illegal, nor—in the Court's view—should they be. Protecting against anticompetitive conduct is an important interest, but so too is the innovation the patent laws are intended to protect. The aim of this Court, like those in *Actavis* and its progeny, is to balance these interests as the law prescribes.

It is not this Court's role, however, to expand the scope of *Actavis* beyond what was contemplated in the Supreme Court's decision. In this case, Plaintiffs' allegations fall short of cognizable anticompetitive conduct. Permitting the claims to go forward would exceed the contours established by *Actavis*, and discourage or needlessly restrict future patent settlements in a fashion not currently supported by law.

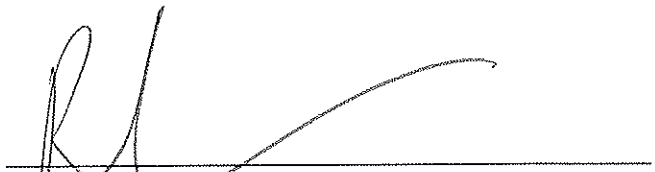
For the foregoing reasons, Defendants' motions to dismiss the Consolidated Amended Class Action Complaint are granted in their entirety. Plaintiffs have previously amended the Complaint three times and further amendment would be futile. Accordingly, dismissal is with prejudice.

[27] Because the Court concludes that the CAC does not state a claim for relief, it declines to address Defendants' state-specific arguments for dismissal, including their argument that Plaintiffs lack standing as indirect purchasers under certain states' laws.

The Clerk of the Court is directed to terminate items 122, 124, 125, and 131 on the docket and to close the consolidated cases listed in footnote 1 of this Opinion.

SO ORDERED.

Dated: September 22, 2015
New York, New York



Ronnie Abrams
United States District Judge