UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION

No. 13-CV-9244 (RA)

OPINION AND ORDER

RONNIE ABRAMS, United States District Judge:

At issue in this case is whether Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively "Takeda") are liable to Plaintiffs, the indirect purchasers of Takeda's diabetes medication called ACTOS, for unlawfully inflating that drug's prices in violation of state antitrust, consumer protection, and unjust enrichment laws. In September 2015, this Court granted Defendants' motion to dismiss. *See* Op. & Order re: Mot. to Dismiss ("2015 Op.") at 51 (Dkt. 221), *available at* 2015 WL 5610752. On appeal from that decision, the Second Circuit largely affirmed the dismissal but also vacated and remanded a small part of the case for additional proceedings. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 102 (2d Cir. 2017).[1] Now before the Court is Plaintiffs' motion to amend their complaint in light of the Second Circuit's decision. For the reasons explained below, Plaintiffs' motion is granted in part and denied in part.

[1] The case originally involved additional defendants (generic-drug manufacturers) and plaintiffs (indirect purchasers of a different Takeda drug called ACTO*plus*). After the Second Circuit's opinion in this case, these parties are indisputably out of the lawsuit. *See* Proposed Am. Compl. ¶¶ 18–32, 162 (Dkt. 238-1).

BACKGROUND

Both this Court and the Second Circuit have recounted this case's factual background and explained the relevant regulatory scheme at length. *See In re Actos*, 848 F.3d at 93–97; 2015 Op. at 1–16. For the purposes of this Opinion, the Court assumes the reader's familiarity with the case and will restate only the basics relevant to this motion.

I. Regulatory Background

This case involves a complicated set of rules set forth in the Hatch-Waxman Act that controls how and when manufacturers of generic drugs can begin competing with brand-name drug producers. Drug inventors may file patents on drug substances, drug products, and methods of using different drugs. Those inventors must also get FDA approval to sell their drugs, however, and thus must file New Drug Applications (NDAs) with the FDA. When the FDA approves such applications, it requires inventors to place the patents related to their NDAs in the FDA's so-called "Orange Book," which lists patents associated with different brand-name drugs. For each patent listed, the Orange Book allows the inventor to describe the patent as involving a drug substance, drug product, or method of use. *See In re Actos*, 848 F.3d at 98–99. If generic-drug manufacturers wish to sell a generic version of a brand-name drug, they must first file an Abbreviated New Drug Application (ANDA) and explain why their generic will not infringe the brand's patents.

There are several ways for generics to show that they will not infringe a brand's unexpired patents under the Act, but two are particularly relevant here. First, if generics are prepared to risk a patent-infringement lawsuit, they can challenge the validity or applicability of the patent by certifying that the brand's patents are "invalid or will not be infringed by" their generic, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"). To incentivize generic manufacturers to challenge invalid patents (and therefore run the risk of being sued by patent holders), the first

generic to file a Paragraph IV certification may receive a 180-day period during which it has the exclusive right to market a generic version of the drug. *See id.* § 355(j)(5)(B)(iv). This exclusivity period can be very lucrative for the generics who successfully challenge patents. Second, if the generic is seeking to market only a new *method of using* a particular drug, it can "carve out" the patented methods of use and proceed with a lower risk of a patent-infringement lawsuit, *id.* § 355(j)(2)(A)(viii) ("Section viii statement"). Successful applications to carve out methods of use under Section viii allow generics to enter the market even during the 180-day exclusivity period held by the first successful Paragraph IV filer. *See In re Actos*, 848 F.3d at 95.

II. Facts of this Case

Starting in the 1980s, Takeda obtained several patents related to its diabetes medicines. The first of those patents, the so-called '777 patent, claimed to invent "pioglitazone," the active ingredient in Takeda's brand-name drug ACTOS. Takeda later acquired two other patents, its so-called '584 and '404 patents, which claimed to invent both combinations of pioglitazone with other drugs and methods of using pioglitazone. To obtain FDA approval to sell ACTOS, Takeda filed a New Drug Application (NDA) in 1999. The FDA approved that application, and Takeda listed its '777, '584, and '404 patents in the FDA's Orange Book. At the time, the Orange Book only allowed one description per patent listed. *See In re Actos*, 848 F.3d at 98–99. Takeda listed the '777 patent as a drug-substance patent and the other two as method-of-use patents. In 1999 and 2002, Takeda allegedly represented to the FDA that the '584 and '404 patents served as drug-product and method-of-use patents related to ACTOS. (By all appearances, these representations were not public information at the time. *See id.*) The '777 patent was due to expire on January 17, 2011, while the '584 and '404 patents would not expire until 2016.

Starting in 2003, several generics began the process of applying to enter the ACTOS market upon the expiration of the '777 patent. The first three companies who sought to compete with ACTOS filed their applications on the same day. These generics, the so-called first filers, challenged the validity or applicability of the '584 and '404 patents to their proposed ACTOS generics by submitting Paragraph IV certifications. They also submitted carve-out statements for Takeda's method-of-use claims under Section viii. Over the following years, six other generics, the late filers, submitted similar applications with both types of certifications. Only one manufacturer—Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva")—submitted an application relying solely on a carve-out statement under Section viii. According to Plaintiffs, Teva did not file a Paragraph IV certification because it believed that Takeda's '584 and '404 patents were in truth patents only for methods of using ACTOS and thus did not need to be challenged under Paragraph IV as a drug-substance or drug-product patent would.

In 2003, Takeda sued the generics who had filed applications with Paragraph IV certifications challenging the validity of its two patents. Six years later, Takeda initiated a separate infringement lawsuit against Teva. Soon thereafter, the FDA received a citizen petition that essentially asked it to deny Teva's Abbreviated New Drug Application on the ground that Teva lacked a Paragraph IV certification. As a result of that petition, in January 2010, Takeda informed the FDA that the '584 and '404 patents had been properly described as both drug-product and method-of-use patents for ACTOS. As a matter of practice, the FDA relies on such representations without independent evaluation. *See In re Actos*, 848 F.3d at 96–97. Based on Takeda's representations, the FDA granted the citizen petition on March 15, 2010. The FDA required all ANDAs for ACTOS generics, including Teva's, to include an appropriate Paragraph IV

certification for the '584 and '404 patents explaining why the generic did not infringe those patents' drug-product claims. *See id.* (citing FDA Resp. to Sandoz Citizen Pet., No. FDA-2009-P-0411-0010 (Mar. 15, 2010)).

Takeda ultimately settled its infringement lawsuits on terms that allowed the first-filing generics (and Teva, to a lesser extent) to begin selling generic versions of ACTOS on August 17, 2012, which was over a year after the '777 patent (which the generics had never challenged) expired and approximately four years before the '584 and '404 patents expired. The other companies were allowed to begin selling generics 180 days later.

III. Procedural History

Plaintiffs are indirect purchasers of ACTOS who sued Takeda and several generic manufacturers under state antitrust laws. They claimed, among other things, that Takeda had unlawfully reaped monopoly profits by delaying the generics' entry into the market. This Court dismissed the complaint on the basis that Plaintiffs had failed to adequately allege that Takeda's actions caused Plaintiffs' antitrust injury.

Plaintiffs appealed, arguing that they had adequately alleged that Takeda's purportedly false representations about its '584 and '404 patents delayed the entry of generic competitors to the ACTOS market, thereby facilitating Takeda's alleged monopoly over the relevant market and causing Plaintiffs' claimed injuries. Plaintiffs argued that they had alleged causation in two alternative ways. As the Second Circuit explained, "[f]or their first theory, plaintiffs argue that Takeda's allegedly false descriptions of its '584 and '404 patents forced the generics to file Paragraph IV certifications, which triggered a 180-day exclusivity period for first-filers and a corresponding 180-day delay (the 'bottleneck') for all subsequent filers." *In re Actos*, 848 F.3d at 98. Plaintiffs' second theory, meanwhile, was based on Teva's delayed entry into the market.

According to Plaintiffs, Teva was delayed due to the FDA's ruling on the citizen petition, in which the FDA required Teva to make a Paragraph IV certification and in so doing explicitly relied on Takeda's allegedly false patent descriptions.

The Second Circuit affirmed this Court's rejection of Plaintiffs' first causation theory, holding that Plaintiffs had failed to plausibly allege that the generics had filed their Paragraph IV certifications with knowledge of Takeda's 1999 and 2002 patent descriptions. The Circuit vacated this Court's decision in part, however, as to Plaintiffs' theory regarding Teva, remanding the case to the "limited extent" that Plaintiffs "plausibly alleged that Takeda delayed Teva's market entry." *Id.*

In light of that decision, Plaintiffs now move for leave to amend their complaint. *See* Pls.' Mot. to Amend Compl. (Dkt. 236). In Plaintiffs' proposed amended complaint, they remove the claims and defendants that this Court and the Second Circuit have dismissed and expand on the remaining theories of causation. As is relevant here, they add allegations to support an assertion that Takeda's conduct delayed the entry of generic manufacturers besides Teva into the ACTOS market. The Takeda entities—the only remaining Defendants—responded in opposition to Plaintiffs' motion for leave to amend, *see* Defs.' Mem. Opp. (Dkt. 239), and Plaintiffs replied, *see* Pls. Reply Mem. (Dkt. 240).

LEGAL STANDARDS

Although courts should "freely give leave [to amend] when justice so requires," they need not grant leave to amend if the amendments would be futile or cause undue delay, among other things. Fed. R. Civ. P. 15(a)(2); *see Passlogix, Inc. v. 2FA Tech., LLC*, 708 F. Supp. 2d 378, 407 (S.D.N.Y. 2010). This Court also may not permit amendments that would violate "the law of the case doctrine . . ., [which] requires a trial court to follow an appellate court's previous ruling on

an issue in the same case." *See United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir. 2002) (citation omitted); *see also Scottish Air Int'l, Inc. v. British Caledonian Grp., PLC.*, 152 F.R.D. 18, 25, 28–29 (S.D.N.Y. 1993). This so-called "mandate rule" prohibits the "re-litigation of issues previously waived by the parties or decided by the appellate court." *United States v. Malki*, 718 F.3d 178, 182 (2d Cir. 2013). If, however, an issue was "not expressly or implicitly part of the decision of the court of appeals," then the district court may consider that issue on remand. *United States v. Cirami*, 563 F.2d 26, 33 (2d Cir. 1977); *see also United States v. Tenzer*, 213 F.3d 34, 42 (2d Cir. 2000) (holding that the mandate rule did not apply in a sentencing context where the prior appellate panel "had no occasion to decide any issues concerning sentencing").

DISCUSSION

As an initial matter, many of Plaintiffs' proposed amendments—including their proposed elimination of the defendants and claims that have already been dismissed—are unopposed, *see* Defs.' Letter at 1 (Dkt. 241), and leave to amend is granted as to those proposed amendments. *See generally* Fed. R. Civ. P. 15(a)(2); *Sullivan v. Lakeram*, No. 13 CIV. 7677 (NRB), 2016 WL 4097856, at *3 & n.3 (S.D.N.Y. July 28, 2016).

Takeda does oppose, however, Plaintiffs' proposed amendments that "raise new claims or theories outside of the one theory" about Teva's delay into the ACTOS market that was "remanded by the Second Circuit." *See* Defs.' Mem. Opp. at 5 (Dkt. 239); *see also* Defs.' Letter at 1 (Dkt. 241). In particular, Takeda challenges all the proposed allegations as to generic applicants other than Teva and as to how Takeda's allegedly false statements purportedly delayed those generics' entry into the ACTOS market. Takeda argues that the Court should reject Plaintiffs' proposed amendments under both the so-called "mandate rule" and Federal Rule of Civil Procedure 15(a). *See* Defs.' Mem. Opp. at 6, 18 (Dkt. 239); Defs.' Letter at 1 (Dkt. 241). The proposed amendments

to which Takeda objects fall into roughly two categories, each of which is addressed separately below.

I. Proposed Amendments Based on Takeda's 1999 and 2002 Patent Descriptions

The first set of proposed amendments relates to Plaintiffs' theory that Takeda's alleged misrepresentations to the FDA in 1999 and 2002 delayed the generic manufacturers' entry into the ACTOS market. Specifically, Plaintiffs now allege a way in which the generics, "even if they did not *originally know* how Takeda described its Patents when the manufacturers *filed* their" applications for approval, "*would have subsequently gained that knowledge* and amended their ANDAs in sufficient time to enter the market earlier than they did." *See* Pls. Mem. at 8 (Dkt. 237) (emphasis in original). According to these proposed amendments, the FDA has a policy of examining whether generic manufacturers have made the proper type of certification (*e.g.*, a Paragraph IV certification) and of requiring generics to correct their certifications if the wrong type has been filed. Plaintiffs thus assert that, in the absence of Takeda's 1999 and 2002 statements, the FDA "would have required any generic manufacturers" who filed both Paragraph IV and Section viii statements to "*amend their certifications to address only the Patents' method-of-use claims*." *Id.* As a result, Plaintiffs contend, any right-minded generic manufacturer "would have promptly made the amendments that the FDA would have required" and further "would have chosen the Section viii route" that would have allowed them to enter the market with carve-out labels in 2011. *Id.* at 4, 10; Proposed Am. Compl. ¶¶ 90–92 (Dkt. 238-1).

There are several problems with these proposed amendments, not least of which is that they are barred by the mandate rule. The Second Circuit directly addressed Plaintiffs' attempts to explain how the generics might have been aware of Takeda's allegedly misleading statements to the FDA in 1999 and 2002. In so doing, it concluded that "there are simply no allegations from

which we can infer that the generics were aware of the alleged false patent descriptions at the core of this case." *In Re Actos*, 848 F.3d at 99. The Circuit further noted how Plaintiffs had "totally failed" to allege any "viable methods" by which the generics could have "learn[ed] of the alleged false patent descriptions," despite having "amend[ed] their complaint several times." *Id.* Now, just as they did on appeal, Plaintiffs are alleging different ways in which the generics could have learned about Takeda's 1999 and 2002 statements. The law of the case precludes such amendments.

Moreover, Plaintiffs' new allegations about the 1999 and 2002 alleged misrepresentations fail to plausibly allege causation for the same reasons that their earlier allegations failed: the causal chain is too speculative. Here, Plaintiffs' argument that the generics would have found out about the 1999 and 2002 statements relies on the FDA's purported policy of telling generics if they had improperly filed certifications and then requiring them to fix those certifications. *See* Proposed Am. Compl. ¶ 78 (Dkt. 238-1). If the FDA had been following such a policy under Plaintiffs' theory of the case, the FDA would have promptly required Teva to amend its ANDA—which included only a Section viii carve-out statement—to include a Paragraph IV statement challenging Takeda's '584 and '404 patents. As even Plaintiffs observe in their proposed amended complaint, however, the FDA failed to follow that purported policy with respect to Teva. *See id.* ¶ 110. Thus, the proposed amendments at best allege that the FDA *sometimes* examined the propriety of generics' certifications.

The Second Circuit explicitly rejected a similarly flawed theory on Plaintiffs' appeal. Plaintiffs had argued then that the generics could have learned of Takeda's alleged misrepresentations by consulting a supplemental filing that Takeda had made to its New Drug Application, which Plaintiffs claimed the FDA made available on its website. The Second Circuit

rejected this argument on the ground that the generics could not "plausibly have learned of the allegedly false patent descriptions . . . by consulting a supplemental Takeda filing on the FDA's website" because the supplemental filing did not have accurate information about both the '584 and '404 patents and thus "was not a dependable source of patent information for generic applicants." *In re Actos*, 848 F.3d at 99. Similarly, the FDA's failure to comply with its own policy of advising generics of incorrect certifications was not a "dependable source of patent information" for the generics, because the FDA applied that policy inconsistently even within the context of this case. *Id.* Thus, it is not plausible that the generics would have relied on the FDA's silence as proof of Takeda's alleged misrepresentations—or even as confirmation that they had filed the proper certifications. Plaintiffs are therefore denied leave to amend to the extent that they seek to add causation theories based on Takeda's allegedly false patent descriptions in 1999 and 2002.

II. Proposed Amendments Based on Takeda's Public 2010 Patent Description and the FDA's 2010 ruling

The second category of amendments poses a closer question. These amendments bear on Plaintiffs' theory that Takeda's response to the 2010 citizen petition—in which Takeda publicly stated its position that the '584 and '404 patents covered the ACTOS drug product—and the FDA's ruling on that petition caused a delay in the generics' market entry. On appeal to the Second Circuit, Plaintiffs argued that they had "adequately allege[d] causation with respect to entry by Teva" even in the event that the Second Circuit accepted Takeda's assertions that the other generics had no knowledge of its patent descriptions. Appellant Reply Br. at 4, available at 2016 WL 2942584 (May 19, 2016). Plaintiffs did not mention any similar alternative theory for the other generics. As to Teva, the Second Circuit approved the theory as plausible:

> [T]his second theory does not depend on Teva's knowledge of Takeda's description of its patents as drug product patents, because the FDA's 2010 announcement was itself expressly based on Takeda's repeated and allegedly false patent descriptions. [citation omitted.] . . . This theory of causation is highly plausible. As noted, the FDA first preliminarily approved Teva's application, then entertained a citizen petition seeking to force all applicants to make Paragraph IV certifications as to the '584 and '404 patents, and then publicly announced that certifications would indeed be required. In so doing, the FDA expressly stated that certifications would be required precisely *because* Takeda had described these patents as drug product patents. In other words, the FDA made no attempt to evaluate whether the descriptions were true, but simply accepted them at face value—thus frustrating Teva's Section viii application. While Teva thereafter sought to challenge the truthfulness of these descriptions in its litigation with Takeda (but settled before the issue was resolved), the damage had been done. A plaintiff could hardly ask for a clearer causal connection.

In re Actos, 848 F.3d at 100 (emphasis in original). The Circuit did not reach the question of whether a related theory could be applied to the other generics besides Teva—presumably because Plaintiffs did not advance such a theory on appeal. Indeed, the parties point to no place in the record where Plaintiffs have previously asserted that the generics' failure to *amend* their certifications (as opposed to the generics' initial decision to make them) caused Plaintiffs' antitrust injury.

Plaintiffs now seek to expand their Teva theory to the other generics. Their proposed amended causal chain goes as follows: (1) "absent Takeda's wrongful conduct, Takeda would have responded" to the citizen petition "by acknowledging that the '584 and '404 Patents claimed only methods of using ACTOS in combination therapy," Proposed Am. Compl. ¶ 82 (Dkt. 238-1); (2) this acknowledgment would have caused either (a) the generic applicants to "promptly withdraw[]" their prior certifications to address only the method-of-use claims, *id.* ¶ 83, or (b) the FDA to respond by requiring the generics to amend their certifications to address only the method-of use-claims, *id.* ¶ 84; (3) under such circumstances, the generics would have had to choose between pursuing Section viii statements or Paragraph IV certifications, not both, *id.* ¶ 89; (4) "[a]s rational profit maximizing entities, all of the generic applicants would have chosen Section viii

rather than Paragraph IV" and would have amended their certifications accordingly, *id.* ¶¶ 90–92; and (5) the generics, with their newly amended Section viii carve-out statements for methods of use, would have been able to enter the market earlier than they did and without regard to any still-existing 180-day exclusivity periods, *id.* ¶ 91.

According to Takeda, these proposed amendments to Plaintiffs' causation theory are barred by the mandate rule because the Second Circuit's mandate was expressly limited to Plaintiffs' theory about Teva. Plaintiffs respond that this theory was never presented to or decided by the Second Circuit with respect to the other generics and is well within the Circuit's mandate.

To resolve this dispute, the Court must "determine whether [the] issue remains open for reconsideration on remand . . . [by] look[ing] to both the specific dictates of the remand order as well as the broader 'spirit of the mandate.'" *United States v. Ben Zvi*, 242 F.3d 89, 95 (2d Cir. 2001) (citation omitted). If the issue was "impliedly resolved by the appellate court's mandate," the parties may not relitigate it on remand. *Yick Man Mui v. United States,* 614 F.3d 50, 53 (2d Cir. 2010). If the "the mandate can reasonably be understood as permitting" the trial court to reopen an issue, however, then whether the party failed to raise the issue at a prior stage of the litigation (and thus waived the issue) is irrelevant to the mandate-rule analysis. *See Quintieri*, 306 F.3d at 1229.

Here, the remand specifically dictates: "because plaintiffs' theory as to Teva does not require any knowledge of the false patent descriptions, we reach other issues as to Teva and find that plaintiffs plausibly alleged that Takeda delayed Teva's market entry. We therefore vacate the judgment of the district court to that limited extent." *In re Actos*, 848 F.3d at 93. In its reasoning, the Second Circuit emphasized that the Teva theory was plausible because it relied on the FDA's ruling in response to the citizen's petition. As the Circuit noted, the FDA ruling included an

"express[] state[ment] that certifications would be required precisely *because* Takeda had described these patents as drug product patents." *Id.* at 100 (emphasis in original). In other words, the Circuit found the Teva theory plausible not on the basis that the generics were aware of Takeda's January 2010 response to the citizen's petition, but rather because the FDA's March 2010 ruling explicitly relied on Takeda's representations.

To the extent that Plaintiffs' proposed amended complaint alleges that other generics would have known about Takeda's purported misrepresentations in January 2010, and that those alleged misrepresentations lulled the generics into continuing to seek Paragraph IV certification, the amendments are outside the scope of the Second Circuit's remand. The Second Circuit rejected—arguably explicitly and at the very least implicitly—the argument that the generics plausibly knew about the January 2010 patent descriptions. The Circuit emphasized that Plaintiffs' theory as to Teva did "not depend on Teva's knowledge of Takeda's description of its patents as drug product patents, because the FDA's 2010 announcement was expressly based on Takeda's repeated and allegedly false patent descriptions." *Id.* Earlier in the decision, the Second Circuit similarly noted that it was vacating as to the Teva theory because it "does not require any knowledge of the false patent descriptions." *Id.* at 93. The Circuit thus found Plaintiffs' theory as to Teva reasonable due to the FDA's ruling, not due to knowledge of Takeda's January 2010 alleged misrepresentations at the time they were made. Accordingly, Plaintiffs' proposed amendments are rejected to the extent they rely on the generics' knowledge of Takeda's January 2010 representations to the FDA.

Plaintiffs do, however, alternatively rely on the FDA's March 2010 ruling as a basis for their causation theory with regard to the non-Teva generics. The Court concludes that these proposed amendments are within the Second Circuit's mandate on remand. The spirit of the mandate, as evidenced by the Circuit's reasoning and its direction that the Court hold "further

proceedings consistent with" its decision, is broad enough to encompass amendments that include more than one way in which the FDA's 2010 ruling harmed Plaintiffs. *Id.* at 102; *see also Sompo Japan Ins. Co. of Am. v. Norfolk S. Ry. Co.*, 762 F.3d 165, 178 (2d Cir. 2014). The Circuit "note[d] in passing" that the Court can consider on remand arguments "that the parties . . . raised on appeal . . . [but had not been] reached by the district court." *In re Actos*, 848 F.3d at 101. And Plaintiffs' proposed amendments—to the extent they allege that Takeda's misrepresentations caused the FDA's ruling and that the FDA's ruling in turn caused a delay in the generics' entry—are consistent with the Circuit's ruling. The proposed amendments also appear plausible as to the non-Teva generics for the same reasons the Circuit identified as to Teva. Although the non-Teva generics were not parties to the citizen petition, the FDA's ruling was a matter of public record which the generics would plausibly have been following with interest given the ruling's potential impact on their own lawsuits and entries into the market. Moreover, if the FDA's ruling had come out the other way and permitted Teva to proceed as it had planned to do, that outcome plausibly would have led the generics to enter the market sooner, as alleged in the proposed amended complaint. At this stage, Defendants have not contended otherwise. Plaintiffs' proposed amendments are therefore within the scope of Second Circuit's mandate on remand to the extent that they allege that the FDA's ruling caused a delay in the generics' market entry.

III. Amendment under Rule 15 of the Federal Rules of Civil Procedure

In the alternative, Takeda argues that the Court should deny leave to amend under Rule 15 of the Federal Rules of Civil Procedure on the basis that Plaintiffs' proposed amendments were made in bad faith, would cause "undue delay," would result in undue prejudice, and were made despite "ample prior opportunity" to do so. Defs.' Mem. Opp. at 18 (Dkt. 239) (citations omitted). "[L]eave to amend," they urge, "may be denied where the moving party knows or should have

known of the facts upon which the proposed amendment is based, but failed to include them in the original pleading." *Zubulake v. UBS Warburg LLC*, 231 F.R.D. 159, 162 (S.D.N.Y. 2005) (citation omitted). Although it is true that Plaintiffs could have been more diligent in advancing their theory regarding the non-Teva generics, courts must "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2); *see Passlogix, Inc.*, 708 F. Supp. 2d at 407. In any event, "it is within the sound discretion of the district court to grant or deny leave to amend" under Rule 15. *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007) (citation omitted).

In light of the relatively early stage of litigation in this case, the Court grants Plaintiffs' motion to amend in the limited manner explained above. Although this case has been pending for just over four years, it has only progressed to the motion-to-dismiss stage. And the types of prejudice to which Takeda points—primarily that the proposed amendments will require additional briefing, delay, and expense—are not, on balance, unduly prejudicial. The proposed amendments are closely enough related to Plaintiffs' prior theories that Takeda is not unfairly disadvantaged by having to respond to them at this point in the litigation. Moreover, the same Defendants must respond to a functionally identical argument in the related direct-purchaser action also pending before this Court. *See In re Actos Direct Purchaser Litigation*, No. 15-CV-3278, Pls.' Mem. Opp. to Defs.' Supp. Briefs at 27 (Dkt. 105) ("[T]he direct purchasers . . . allege that Takeda's wrongful listing information caused *the FDA* to impose on *all generic makers* . . . a requirement that they certify to the combination product claims in the '584 and '404 patents. There was nothing special about the FDA having imposed that requirement upon Teva . . . [and] this theory is wholly independent of any knowledge of the generic filers." (emphasis in original) (footnotes omitted)). Thus, in the interests of justice and in the absence of undue prejudice or delay, Plaintiffs may expand their causation allegations in the limited fashion described above.

CONCLUSION

For the foregoing reasons, Plaintiffs are granted leave to amend their complaint to the extent that the amendments are unopposed or allege causation based on the FDA's March 2010 ruling. Plaintiffs shall file an amended complaint in compliance with this decision no later than March 12, 2018. At that time, they shall also submit to opposing counsel and the Court a redlined version showing the changes between the new proposed amended complaint and the prior Consolidated Amended Class Action Complaint (Dkt. 120).

SO ORDERED.

Dated: February 12, 2018
New York, New York

Ronnie Abrams
United States District Judge