UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISANA INC., DAVID MITCHELL, *individually and on behalf of all others similarly situated*,

Plaintiffs,

– *against* –

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, *and* JEROME ZELDIS,

Defendants.

OPINION & ORDER

23-cv-7871 (ER)

NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated,

Plaintiffs,

– *against* –

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, *and* JEROME ZELDIS,

Defendants.

24-cv-02230 (ER)

CENTERWELL PHARMACY, INC.,

Plaintiff,

– *against* –

CELGENE CORPORATION, *and* BRISTOL MYERS SQUIBB COMPANY,

Defendants.

24-cv-06924 (ER)

RAMOS, D.J.:

Plaintiffs Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana ("Louisiana Health"), HMO Louisiana, Inc., and David Mitchell[1] (collectively, "Plaintiffs"), bring this putative class action against Celgene Corporation, Bristol Myers Squibb Company, Anthony Insogna, and Jerome Zeldis[2] (collectively, "Defendants"), alleging unlawful monopolization under 15 U.S.C. § 2 and state law. Doc. 72. Additionally, Plaintiffs allege violations of consumer protection laws and unjust enrichment against Celgene.[3] *Id.*

Before the Court is Plaintiffs' motion for leave to file a Second Amended Complaint ("SAC"),[4] as well as Defendants' motion to strike Appendix A and Appendix B of Plaintiffs reply to the motion for leave to amend. Docs. 162, 181. For the reasons set forth below, Plaintiffs' motion is DENIED and Defendants' motion to strike the excess pages in Plaintiffs' reply brief is GRANTED.

I. BACKGROUND

[1] Plaintiffs informed the Court on February 6, 2026 that David Mitchell, the putative class representative for the proposed consumer subclass, passed away. Doc. 185. Plaintiffs have not yet moved for an order to substitute the class representative.

[2] Plaintiffs do not intend to rename Dr. Zeldis or Mr. Insogna as defendants in the SAC. Doc. 164 at 5 n.2.

[3] After the filing of the instant motions to dismiss the first amended complaint, two other cases asserting similar claims against the same defendants were consolidated with this case: *New York Hotel Trades Council & Hotel Association Of New York City, Inc.*, *Health Benefits Fund v. Celgene Corp., Bristol Myers Squibb Co., Anthony Insogna, and Jerome Zeldis*, 24-cv-02230 and *Centerwell Pharmacy, Inc. v. Celgene Corp. & Bristol Myers Squibb Co.*, 24-cv-06924. Docs. 124, 150. The consolidated plaintiffs are parties to the instant motions. Doc. 164 at 5 n.1. However, Plaintiff notes that "[d]ue to third parties' refusal to consent for counsel for CenterWell to access the same three settlement agreements previously disclosed to the end purchaser plaintiffs, CenterWell [filed] an identical motion, proposed order, and memorandum of law, but attaching a [] proposed First Amended Complaint that omits confidential information to which it has not had access and (as a direct purchaser) paragraphs regarding indirect purchasers." *Id.* Plaintiffs clarified that "[a]ll arguments set forth in this motion for leave to amend can be made with reference to the end payor plaintiffs' SAC." *Id.*

[4] Unless otherwise noted, citations to "¶ _" refer to Plaintiffs' proposed SAC, Doc. 164-1.

A. Overview

The facts underlying this case are described in detail in this Court's March 31, 2025 Opinion and Order (the "March 2025 Opinion") granting Defendants' motions to dismiss. Doc. 155. For present purposes, the Court provides an abbreviated summary.

Louisiana Health is a not-for-profit health insurance company that provides and manages the health benefits of more than one million members. ¶ 6. HMO Louisiana, Inc. is a domestic health maintenance organization that is a wholly owned subsidiary of Louisiana Health. ¶ 7. David Mitchell is an individual who had multiple myeloma. ¶ 8. New York Hotel Trades Council & Hotel Association of New York City, Inc., Health Benefits Fund ("NYHTC") provides health benefits to over 85,000 Union members, dependents and retirees of the New York City hotel industry. ¶ 9. Bristol Myers Squibb Company and Celgene Corporation (collectively, "Celgene") are pharmaceutical companies that are organized and existing under the laws of the State of Delaware. ¶¶ 10–11. In 2019, Celgene was acquired by Bristol Myers. ¶ 11. Celgene sells Pomalyst, a multi-billion dollar a year drug used to treat multiple myeloma. ¶ 1.

Anthony Insogna resides in San Diego, California, and is a partner at the law firm Jones Day. Doc. 72 ¶ 11; ¶ 142. Insogna has represented Celgene since 1996 and is alleged to have been directly involved in the procurement of certain fraudulently obtained patents. Doc. 72 ¶ 11.

Jerome B. Zeldis, M.D., PhD, resides in Princeton, New Jersey, Doc. 72 ¶ 12, and became a Celgene executive in 1997, ¶ 143. During his tenure at Celgene, Zeldis served as Vice President of Medical Affairs and Chief Medical Officer. ¶ 143. Zeldis is alleged to have applied for, and obtained, some of the patents alleged in the complaint to have been fraudulently obtained. ¶¶ 143–44.

Plaintiffs are customers of pharmacies which initially purchased pomalidomide—a drug used in the treatment of multiple myeloma and sold under the brand name

Pomalyst—from Celgene, or entities who reimbursed unspecified customers of such pharmacies. Doc. 109 at 22.

Plaintiffs' contend that Celgene unlawfully extended a monopoly in the market for Pomalyst. ¶ 1. According to Plaintiffs, Defendants accomplished this (i) through a pattern of fraud on the U.S. patent office, (ii) by abuse of the federal judicial system, and (iii) by eventually settling with generic competitors for extended delay of generic entry for years through agreements that protect unlawful supra-competitive pricing. *Id.* The result, they contend, is that purchasers have overpaid—and continue to overpay—for this drug. *Id.*

B. Statement of Facts

1. Celgene's Alleged "Scheme"

Plaintiffs allege that Celgene fraudulently obtained certain patents covering Pomalyst in order to obtain monopoly power over the relevant market for that drug (the "*Walker Process* Fraud Allegations").[5] ¶ 1, 5, 44–102. Specifically, they allege that Celgene fraudulently obtained the following patents: (1) U.S. Patent Number 8,828,427, (the "'427 Patent"), U.S. Patent Number 9,993,467 (the "'467 Patent"), and U.S. Patent No. 10,555,939 (the "'5939 Patent"), which cover the formulations for pomalidomide; (2) U.S. Patent No. 8,198,262, (the "'262 Patent"), U.S. Patent No. 8,673,939 (the "'3939 Patent"), and U.S. Patent No. 8,735,428 (the "'428 Patent"), which cover the methods of using pomalidomide to treat multiple myeloma; and (3) U.S. Patent No. 10,093,647, (the "'647 Patent"), U.S. Patent No. 10,093,648 (the "'648 Patent"), and U.S. Patent No.

[5] In *Walker Process,* the Supreme Court held that "the maintenance and enforcement of a patent obtained by fraud on the [PTO]" may form the basis of an action under Section 2 of the Sherman Act. *See Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 173–74 (1965). To plead a claim for relief under Section 2 of the Sherman Act on a *Walker Process* theory, a plaintiff must allege two conditions. "First, the plaintiff must show that the defendant procured the relevant patent by knowing and willful fraud on the [PTO] or (in the case of an assignee) that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012). "Second, the plaintiff must prove all the elements otherwise necessary to establish a Sherman Act monopolization charge." *Ritz Camera & Image,* 700 F.3d at 506 (citations omitted).

10,093,649 (the "'649 Patent"), which cover polymorphic forms of pomalidomide.[6] ¶ 203–05, 268, 342. Plaintiffs allege that Celgene, as part of their overall "scheme," asserted those fraudulently obtained patents against its competitors through sham litigation to prevent competition, and then unlawfully settled with competitors in exchange for their delayed entry in the pomalidomide market. ¶¶ 113–17, 124–25, 128–30. The simultaneously agreed upon delayed entry, Plaintiffs argue, will result in substantial damages in the form of overcharges through at least early 2026. ¶ 552. Previously, the Court outlined the allegations related to each of these patents. Doc. 155. Below, as relevant to the instant motions, the Court reiterates the *Walker Process* fraud allegations, as well as allegations pertaining to the alleged sham lawsuits and the Pomalyst delay.

2. The Walker Process Fraud Allegations

Starting on August 19, 2008, Celgene would pursue nine patents with the PTO that Plaintiffs allege were either obtained through fraud or are otherwise invalid. ¶¶ 202–66, 325. On February 8, 2013, the FDA first approved the marketing of pomalidomide, sold under the brand name Pomalyst, for 1–4 mg capsules. ¶¶ 1, 266. Pomalyst was approved as a new chemical entity ("NCE"), which granted Celgene a 5-year exclusivity from generic entry in the pomalidomide market, until February 8, 2018. ¶¶ 266, 267, 325.

a. The Method of Treatment Patents

Plaintiffs allege that Celgene intentionally misrepresented and omitted material facts before the PTO to obtain the '262, '3939 and '428 patents, which cover methods for using pomalidomide to treat multiple myeloma. ¶¶ 203–05.

[6] Polymorphism refers to the ability of a chemical compound to crystallize into different three-dimensional crystal structures. Doc. 72 ¶ 262 n. 89.

The '262 Patent

As further described in the March 2025 Opinion, Plaintiffs set forth the following allegations. On August 19, 2008, Celgene, along with co-conspirators Insogna and Zeldis, applied for what would become the '262 patent. ¶ 219. The patent examiner rejected the application because a combination of prior art references disclosed the cyclical treatment of multiple myeloma with pomalidomide, including the '517 patent and Davies (2001)."[7] ¶¶ 158–160, 222–23. To overcome the rejection, according to Plaintiffs, Celgene misrepresented or omitted the truth about the '517 patent, Davies (2001), and "D'Amato (2001)."[8] ¶¶ 231–39. First, on December 23, 2010, Insogna attested, "[t]he PTO admits that the primary reference [the '517 patent] does not teach [pomalidomide]." ¶ 226. However, Celgene knew the '517 patent did teach pomalidomide because, for example, it was the foundational patent that claimed Celgene's profitable drug, Revlimid, the brand name for the drug compound lenalidomide, which is also used to treat multiple myeloma. ¶ 141. Second, Celgene allegedly repeated the examiner's "mistaken belief" that Davies (2001) did not teach pomalidomide, by capitalizing on the confusion created by the article's use of immunomodulatory drugs ("IMiDs")—terminology coined by Celgene. ¶¶ 163, 233. Third, Celgene "misdirect[ed]" the examiner by arguing that the two patents the examiner cited, the '230 and '554, did not teach the use of pomalidomide to treat cancer, while concealing that D'Amato (the '539 patent application) and D'Amato 2001 *did* specifically teach the use of pomalidomide to treat multiple myeloma and other cancers. ¶¶ 233, 234, 236.

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[7] Davies (2001) is prior art research by Davies FE, that allegedly taught that immunomodulatory drugs, including pomalidomide, can be used to treat multiple myeloma and relapsed/refractory disease. ¶¶ 163, 233.

[8] D'Amato (2001) is prior art research by D'Amato, that allegedly taught the specific thalidomide analog pomalidomide for the treatment of multiple myeloma. ¶ 168.

In August 2011, the examiner again rejected the '262 application.[9] ¶ 245. To overcome this rejection, according to Plaintiffs, Celgene made four more false misrepresentations or omissions. ¶¶ 247–54. First, Celgene stated "there is no suggestion in the art that pomalidomide is effective to treat multiple myeloma[.]" ¶ 247. But D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), and Schey (October 2002), all taught that pomalidomide is effective to treat multiple myeloma. ¶ 247. Second, Celgene suggested that the use of one thalidomide compound over another had not been publicly disclosed, including falsely stating: "Davies does not teach or suggest that pomalidomide is more effective than thalidomide in the treatment of multiple myeloma. There would be no basis in Davies to select one compound over the other." ¶ 248. However, Davies (2001) taught that new thalidomide analogs, including IMiDs are 50,000 times more potent in inhibiting TNFα as compared to thalidomide. *Id.* On February 25, 1999, Bruce Collins, counsel for Celgene, submitted the signed declaration of Celgene senior executive David Stirling asserting: "I conclude that Compound 2 is >10,000 fold more active than Compound 1 in this primary human cell-based assay." ¶ 249. "Compound 2" is identified in the Stirling Declaration as pomalidomide. *Id.* Third, Celgene misrepresented that treating cancer with pomalidomide by dosing cyclically was novel, when in fact, it was routine. ¶ 251. Specifically, Celgene stated: "[t]hese publications clearly demonstrate unexpected results of the claimed therapy for relapsed or refractory multiple myeloma." *Id.* Fourth, Celgene misrepresented that the law required that the five references be combined to obtain the claimed invention, when, in reality, any of the references taught the crux of the claimed invention. ¶¶ 252–253. Specifically, Celgene asserted that combining the five references cited by the examiner (Kyle, Davies, Corral, Muller, and the '554) involved "impermissible hindsight," "elements of the

[9] The examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat [multiple myeloma] with pomalidomide as suggested by [Kyle (2001), Davies (2001), Corral (1999), and Muller (1999)[.]" ¶ 245.

claimed method are simply missing from even a combination of the five cited references," and "[t]he mere need to use five references to arrive at the claimed invention is an indication of its lack of obviousness." ¶ 252. On April 9, 2012, the examiner issued the '262 patent. ¶ 261.

The '3939 & '428 Patents

On March 1, 2013, Celgene filed two additional applications for method-of-use patents regarding pomalidomide, both of which addressed the cyclical dosing of pomalidomide. ¶ 287–288. Zeldis was the first-named inventor on both applications. ¶ 287. In July 2013, the examiner rejected the applications as double patenting of the '262 patent and as obvious over the prior art, including Kyle (2001), Davies (2001), Corral (1999), Muller (1999), and the '554 patent. ¶ 293.

The patent examiner conducted an interview with Celgene representatives on October 4, 2013, the summary of which noted that, to overcome the rejection, the "Applicant submitted that the claims, as is, are patentable because pomalidomide (POM) alone was shown to unexpectedly treat multiple myeloma that is or has become resistant to lenalidomide (LEN) … Applicant submitted that one of ordinary skill in the art would not have recognized this because, inter alia, the compounds are so close in structure." ¶ 294. Plaintiffs allege that this assertion by Celgene and its representatives led examiners to believe that Celgene had demonstrated unexpected results supporting a claim of patentability. ¶ 295.

Celgene filed a sworn declaration from its executive Dr. Anjan Thakurta (the "Thakurta Declaration"), on October 9, 2013, asserting that treating refractory or relapsed multiple myeloma with pomalidomide would have been surprising and unexpected. ¶ 297. However, using pomalidomide to treat refractory or relapsed multiple myeloma was known, and Celgene had already disclosed that pomalidomide was more potent than other thalidomide analogs. ¶¶ 299, 300. Plaintiffs allege that Thakurta made these deceptive representations and omissions with the intent to deceive the patent examiner, and that the

examiner justifiably relied on the information provided by Thakurta, as evidenced by the examiner's reversal of its prior decisions rejecting the patents, allowing the patents to issue after Thakurta submitted his declaration. ¶ 301.

Also on October 9, 2013, Celgene and its agents submitted Remarks responding to the examiner's prior rejection of the patent application for the '428 patent, among many things, reiterating that "one skilled in the art would not have expected that pomalidomide would be able to treat multiple myeloma that is relapsed after or refractory to prior treatment." ¶ 302. In reliance on Celgene and Thakurta's misrepresentations and omissions regarding unexpected results, according to Plaintiffs, the examiner issued the '3939 and '428 method of treatment patents on March 18, 2014 and May 27, 2014, respectively. ¶ 309.

b. The Formulation Patents

Similarly, Plaintiffs allege that Celgene intentionally misrepresented and omitted material facts before the PTO to obtain the '427, '467, and '5939 patents, which cover formulations of pomalidomide. ¶ 268.

The '427 Patent

On May 19, 2010, Celgene and Insogna filed a patent application claiming an oral dosage form of a certain weight comprised of pomalidomide and a pharmaceutically acceptable carrier or excipient. ¶ 273. Plaintiffs suggest that this patent was basically a recipe: "combine pomalidomide with a few well-known carriers and excipients (such as mannitol, pregelatinized starch, and sodium stearyl fumarate) in specified ratios." Doc. 127 at 18. Both the instructions and ingredients had been known for years. *Id.* The examiner rejected the patent application multiple times for obviousness, including in light of studies, patents, and a textbook. ¶ 274. To overcome this rejection, Celgene and Insogna made false statements and omitted material information, including the fact that earlier studies, such as Schey (June 2002), disclosed the acceptable dosage amount for pomalidomide (up to 5mg/day). ¶ 276.

After the examiner's second rejection, Celgene and Insogna filed the declaration of a Celgene scientist, Anthony Tutino (the "Tutino Declaration"), stating that many pomalidomide-excipient combinations he tested posed stability issues over time, but that the claimed invention did not. ¶ 279. The Tutino Declaration included "data ostensibly supporting Celgene's assertion of patentability based on 'unexpected results,'" but failing to specify when the reported testing was conducted. ¶ 279. But thalidomide and its analogs, according to Plaintiffs, are notoriously unstable; they degrade in the presence of water, a fact that had been well known and documented in the scientific community for decades. ¶ 279. Accordingly, there was nothing "unexpected" given that "Thalidomide is notoriously unstable due to hydrolysis." ¶ 279. Plaintiffs argue that these allegedly misleading statements led the examiner to allow the '427 patent to issue, noting that the "applicant showed in a declaration that stability of pomalidomide in formulation comprising various excipients is not predictable. The prior art of record is silent with respect to stability of pomalidomide when combined with various excipients." ¶ 282 (emphasis omitted).

The '467 & '5939 Patents

On December 23, 2015, Celgene applied for a patent claiming formulations in terms of relative weight. ¶¶ 310–11. The named inventor on the patent application was Tutino. *Id.* The patent examiner repeatedly rejected the claims as obvious over the prior art. ¶ 312. In response, Celgene amended its claims requiring that the starch to mannitol ratio be from 1:1 to 1:1.5 and submitted another allegedly fraudulent declaration by Tutino that claimed "surprising and unexpected" stability results. ¶ 319. According to Plaintiffs, Celgene's deception worked and on March 15, 2018, the examiner allowed the '467 formulation patent to issue, subject to a terminal disclaimer[10] as to the '427 patent. ¶ 320.

[10] A terminal disclaimer is when the inventor agrees to having a second patent terminate upon the expiration date of the first patent.

On May 10, 2018, Celgene filed another application, for what would eventually lead to the '5939 patent, claiming slightly broader ranges of relative weight compared to the '467 patent. ¶¶ 367–68. The examiner rejected the application four times. ¶ 369. Celgene resubmitted the Tutino Declarations, again claiming "unexpected results." ¶ 370. According to Plaintiffs, the examiner only allowed the patent to issue subject to a terminal disclaimer, which required the patent term to end when the '427 and '467 patents expired. ¶ 371. Further, they contend that the '5939 patent, which was nearly identical to the '467 patent, is invalid as obvious over the prior art and, as with the other formulation patents, was exceedingly easy to design around. ¶ 372.

c. The Polymorph Patents ('647, '648, and '649)

On December 20, 2017—approximately nine months after Celgene received seven paragraph IV certification[11] letters describing the generic Pomalyst Abbreviated New Drug Application ("ANDA")[12] products in detail—Celgene filed three patent applications that would ultimately lead to the '647, '648, and '649 patents.[13] ¶¶ 342, 348, 381. They issued on October 9, 2018. ¶ 381. Each has a single independent claim,

[11] Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), a paragraph IV certification requires that a generic manufacturer's ANDA certify that "[t]hat any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product." ¶ 28.

[12] An ANDA "relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original [New Drug Application] and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand." ¶ 19.

[13] Plaintiffs allege that at least nine generic ANDAs have been filed at as of when they filed the instant motion. ¶ 327. Celgene received paragraph IV certification letters from each as follows (listed in order of ANDA number): Teva (March 30, 2017), Natco and Breckinridge, who partnered in the creation of a Pomalyst ANDA (April 11, 2017), Apotex (March 30, 2017), Hetero (March 29, 2017), Par (April 12, 2017), Aurobindo (April 12, 2017), Mylan (April 6, 2017), Synthon and Alvogen, who partnered in the creation of a Pomalyst ANDA (May 4, 2018), and Dr. Reddy's Laboratories (May 31, 2019). ¶¶ 327, 367. Of the nine generic manufacturers, at least seven are first filers, *i.e.*, filed their ANDA on the first day, February 8, 2017, and are therefore eligible to enter the generic Pomalyst market with a 180-day exclusivity period, if approved. ¶ 326 n. 146. Synthon/Alvogen filed in 2018, while Dr. Reddy's filed in 2019. ¶¶ 326 n. 146, 375.

for a dihydrate, hemihydrate, or monohydrate form, respectively, identified by an x-ray powder diffraction pattern.[14] ¶¶ 344–47.

3. Sham Litigation

Plaintiffs allege that Celgene, having procured the above nine patents, knowingly filed four "waves" of sham lawsuits between May 4, 2017 and March 10, 2020, against all nine Pomalyst generics that submitted paragraph IV certification letters. ¶¶ 325, 373, 381, 393. They allege the lawsuits claimed infringement of the patents but were instead a tactic to prevent competition in the market for generic Pomalyst. ¶ 331. Plaintiffs allege that Celgene's litigation against the generic manufacturers for infringement of the '262, '428, '3939, and '427 was a sham for the independent reason that there was no legitimate or objective basis to assert that the method of treatment patents or the formulation patent were valid and infringed. ¶ 333. They add that even if the formulation patents were somehow valid, a brand company in Celgene's position could not reasonably expect to prove that the '427 was infringed because the '427 is a simple patent claiming a finite combination of ingredients and weights. ¶ 336.

According to Plaintiffs, Celgene achieved its objective in filing the sham lawsuits by creating an unwarranted delay in generic entry, *i.e.*, in addition to the New Chemical Entity ("NCE") 5-year exclusivity,[15] Celgene obtained a 30-month delay of FDA approval of the ANDAs, and ultimately obtained settlement agreements with all nine generics, further delaying entry into the market. ¶¶ 330, 337, 591.

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[14] A hydrate is a compound containing water. Doc. 127 at 19 n. 37. The prefix indicates the number of water molecules to each molecule of water. *Id*.

[15] NCE exclusivity applies to products containing chemical entities never previously approved by the FDA either alone or in combination. ¶ 25. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety— the core molecule or ion of a drug that is responsible for the physiological or pharmacological action of a drug substance—for five years from the date of the NDA's approval. *Id.* However, pursuant to 21 U.S.C. § 355(j)(5)(F)(ii) and 21 C.F.R. § 314.108(b)(2), if the ANDA contains a certification of patent invalidity or non-infringement, an application may be submitted after four years. *Id.* n. 10.

4. The Reverse Payment Allegations[16]

By the fall of 2020, Celgene was allegedly threatened with imminent generic entry for Pomalyst in the United States. ¶ 406. First, the FDA was no longer barred from granting ANDA final approval to the ANDA first filers since both the NCE exclusivity period and the 30-month litigation stay had expired on February 8, 2017, and August 8, 2020, respectively. ¶¶ 407, 408. On October 30, 2020, the FDA granted final approval to the Aurobindo and Natco/Breckenridge ANDAs,[17] ending any FDA-imposed regulatory barriers preventing them from immediately launching their generic product.[18] ¶ 410. Finally, Plaintiffs assert that Celgene was confronted with the fact that their Pomalyst patents were likely to be held invalid and not infringed by the Pomalyst ANDA first filers in the pending lawsuits because they were fraudulently obtained. ¶ 411. Rather than allow generic entry, starting in November 2020, Celgene began entering into settlement agreements with generics, allegedly with reverse payments to "pay off its would-be pomalidomide competitors to have them delay generic entry for about six years, until early 2026." ¶ 414.

Pomalyst Settlement Agreements

The FAC alleges facts regarding the agreements to settle then-pending Pomalyst patent lawsuits between Celgene and three ANDA first filers—Natco/Breckinridge, Teva,

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[16] A typical reverse payment happens when: "Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars." *Actavis*, 570 U.S. at 140. Such agreements may be unlawful because two competitors agree not to compete and thereby unlawfully and unreasonably allocate market power. *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, No. CV 19-7532 (ES) (MAH), 2024 WL 2861865, at *7 (D.N.J. June 6, 2024). A reverse payment need not necessarily be in cash form. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403–09 (3d Cir. 2015). An agreement may still be an unlawful "reverse payment" where it involves an unexplained large transfer of value from the patent holder to the alleged infringer. *Id.* at 409.

[17] Teva was granted final FDA approval of their Pomalyst Abbreviated New Drug Application ("ANDA") number on May 4, 2022. ¶ 449.

[18] At the time of the settlement agreements, it was unclear whether these generics would be entitled to the 180-day exclusivity period: Aurobindo and Natco/Breckenridge had failed to get tentative approval within 30 months of filing its ANDA, potentially jeopardizing their 180-day exclusivity period. ¶ 410 n. 168.

and Aurobindo. ¶¶ 414–463. Celgene entered into the agreements with Natco/Breckinridge (the "Celgene-Natco/Breckinridge Agreement") in November 2020, Teva (the "Celgene-Teva Agreement") in March 2021, and Aurobindo (the "Celgene-Aurobindo Agreement") on July 16, 2021. ¶¶ 444, 451. "The terms of th[ose] arrangement[s] were in part reflected in documentation, but also by the combined *de facto* economics of the industry and incentives created by the agreement." ¶ 444. Specifically, the SAC alleges that in exchange for simultaneously timed generic entry in the market for Pomalyst in early 2026 by the Pomalyst ANDA first filers, the settlement agreements included terms that provided for large, unjustified payments. ¶¶ 417–430, 444–463. These payments consist of a monopoly profit share from a separate, unlawfully allocated market regarding another Celgene drug, Revlimid, as well as most favored entry clauses and contractually granted exclusivity rights in the generic Pomalyst market. *Id*.

Payment Valuation

According to the SAC, the value of the settlement payments that Celgene made to Teva and Aurobindo were "magnitudes" larger than Celgene's avoided litigation expenses. ¶¶ 445, 455. Plaintiffs further allege that "eight litigating Pomalyst ANDA sponsors (Natco, Teva, Dr. Reddy's, Mylan, Apotex, Alvogen, Aurobindo, and Hetero) received large and unjustified reverse payments in their generic Revlimid patent settlement agreements." ¶ 481. These allegedly large and unexplained payments are:

1. Natco/Allergan collaboration: Natco received ~$660 million and Teva received ~$770 million;
2. Mylan, Alvogen, Apotex: $400 million to each;
3. Dr. Reddy's: at least a $400 million (but likely an additional $800 million); and
4. Aurobindo and Hetero: $160 million (approximately $216–$259 million) each.

¶¶ 482–87.

In exchange for the reverse payments, Plaintiffs allege that the ANDA first filers allegedly agreed to delay entry of their Pomalyst generics until "first quarter of 2026." ¶¶ 430–31, 441, 444, 447–48, 452, 548–49. However, according to Plaintiffs, absent Celgene's anticompetitive conduct, they would have launched as early as October 30, 2020. ¶¶ 550. Specifically, Plaintiffs assert that "under competitive conditions, a reasonable generic company in the positions of the generic companies would have (i) launched generic Pomalyst after prevailing at trial, (ii) launched at risk[19] at some point after obtaining final approval, or (iii) entered into an arm's length, payment-free agreement that provides for unrestricted sales and/or an earlier, risk-adjusted, agreed entry date." ¶ 551. Celgene, by unlawfully extending its monopoly in the market for Pomalyst until early 2026, has "forced [Plaintiffs] to purchase brand Pomalyst at supra-competitive prices through at least that time." ¶ 548.

C. Procedural Background

Plaintiffs commenced this action by filing a complaint on September 5, 2023, against Celgene, Bristol Myers, Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Eugia Pharma Specialties Limited, Breckenridge Pharmaceutical, Inc., Natco Pharma Limited, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Limited. Doc. 1. The complaint alleged six counts: Counts I, III, and VI were against Celgene and Bristol Myers for (1) unlawful monopolization in violation of 15 U.S.C. § 1, (2) monopolization under state law, and (3) unjust enrichment under state law. *Id.* at 103, 106, 117. Counts II, IV, and V were brought against all defendants for (1) contract, combination, or conspiracy in restraint of trade in violation of

[19] According to the SAC, an ANDA first filer with final FDA approval may launch its product "at-risk," even if the patent litigation is still pending. ¶ 30. The "risk" being that the generic manufacturer will have to pay the brand manufacturer its lost profits if the generic manufacturer launches its generic and later loses the patent litigation. *Id.* However, the SAC asserts that the generic is highly incentivized to launch at-risk where it expects to ultimately prevail in the patent litigation. *Id.*

15 U.S.C. § 1, (2) contract, combination, or conspiracy to restrain trade under state law, and (3) violations of state consumer protection laws, respectively. *Id.* at 105, 110, 113.

On December 19, 2023, Plaintiffs filed the FAC, alleging six counts: Counts II, III, and VI are against Celgene and Bristol Myers for (1) monopolization under state law, (2) violations of state consumer protection laws, and (3) unjust enrichment under state law, respectively. Doc. 72 at ¶¶ 415–445, 473–695. Count I, IV, and V are brought against all remaining Defendants for unlawful monopolization in violation of 15 U.S.C. § 1 and state law. *Id.* at ¶¶ 403–414, 446–472.[20]

Defendants Celgene, Insogna, and Zeldis filed separate motions to dismiss the FAC on March 21, 2024. Docs. 108, 117, 120. Celgene alleged that Plaintiffs failed to plausibly plead (1) an anticompetitive reverse payment, (2) *Walker Process* fraud on the PTO office, and (3) sham litigation. Docs. 109 at 6, 25, 43; 129 at 2, 13, 16. Insogna alleged that Plaintiffs (1) have failed to state a claim pursuant to Section 2 of the Sherman Act, (2) have failed to state a claim for monopolization pursuant to state law, and (3) are time-barred from pursing their claims. Docs. 118 at 6, 16, 17; 130. Zeldis alleged that Plaintiffs have (1) failed to plausibly plead that the Court has personal jurisdiction over him, (2) failed to state a claim pursuant to Section 2 of the Sherman Act, (3) failed to state a claim for monopolization pursuant to state law, and (4) are time-barred from pursing their claims. Docs. 121 at 5, 11, 13, 14; 131. Notices of supplemental authority were filed with the Court by Celgene and Plaintiffs, Docs. 134, 135, 140, 145, 148, 149, after the briefing was completed on Defendants' motions to dismiss.

On April 18, 2024, Plaintiffs requested that Zeldis' motion be held in abeyance so that they could seek limited jurisdictional discovery from him. Doc. 126. On May 8,

[20] On October 2, 2024, Plaintiffs voluntarily dismissed defendants Teva Pharmaceuticals USA and Teva Pharmaceutical Industries Limited. On October 19, 2024, Plaintiffs voluntarily dismissed defendants Natco Pharma Limited, Breckenridge Pharmaceutical, Inc., and Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited. Docs. 73–75, 78–80. On that same day, October 19, 2024, they amended the complaint to include defendants Anthony Insogna and Jerome Zeldis. Doc. 72.

2024, Plaintiffs filed a letter motion requesting a conference for leave to serve jurisdictional discovery. Doc. 132. The Court held a pre-motion conference on May 31, 2024, where Zeldis was directed to submit supplemental letter briefing by Monday, June 3, 2024, with Plaintiffs' response due by Tuesday, June 4, 2024. In a July 9, 2024 Order, the Court denied Plaintiffs' request for jurisdictional discovery, holding that their allegations are based "on speculation that [Zeldis] could have transacted business giving rise to their claims while in New York," Doc. 147 (quoting Doc. 136), and that they had not alleged a genuine issue of jurisdictional fact warranting limited jurisdictional discovery, *Id.*

The Court issued an Opinion and Order on March 31, 2025, granting Defendants' motions to dismiss for failure to state a claim pursuant to Section 2 of the Sherman Act, and analogous state law claims, and granting Zeldis' motion to dismiss for lack of personal jurisdiction. Docs. 152, 155.

Plaintiffs filed a letter requesting permission to file a motion for leave to file a SAC on April 3, 2025. Doc. 153. Plaintiffs filed the instant motion for leave to file the SAC on May 16, 2025. Doc. 162. In response, Defendants filed their opposition brief on June 27, 2025. Doc. 169.

Plaintiffs sought leave to file a 25-page reply, but the Court permitted 15 pages. Doc. 173. Plaintiffs filed a 15-page reply with two appendices (Appendix A and Appendix B), bringing the total page count to 37 pages. Doc. 174. Celgene then filed a motion to strike Appendix A and Appendix B to Plaintiffs' reply brief in support of their motion for leave to file the SAC on July 31, 2025. Doc. 181.

II. LEGAL STANDARD

A. Motion to Strike

Federal Rule of Civil Procedure 12(f) allows a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Motions to strike are generally disfavored. *County Vanlines Inc. v.*

Experian Information Solutions, Inc., 205 F.R.D. 148, 152 (S.D.N.Y. 2002). Thus, "courts should not tamper with the pleadings unless there is a strong reason for so doing." *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976).

However, "[i]t is within the Court's inherent discretion to strike excessive pages." *Freeman v. Deebs-Elkenaney*, No. 22-cv-02435 (LLS) (SN), 2024 WL 3634738, at *10 (S.D.N.Y. Aug. 1, 2024) (internal quotation marks omitted). Courts in this district have struck parties' submissions in cases where the parties violated a Court's individual practices. *See, e.g.*, *Andrews v. Freemantlemedia N.A., Inc.*, No. 13-cv-5174 (NRB), 2014 WL 6686590, at *15 (S.D.N.Y. Nov. 20, 2014), *aff'd sub nom. Andrews v. Fremantlemedia, N.A., Inc.*, 613 F. App'x 67 (2d Cir. 2015) (striking plaintiffs' motions where they expressly conceded they did not comply with the pre-motion conference requirements); *Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 464 n.4 (S.D.N.Y.2010) (decrying a "thinly veiled attempt to skirt [the page limits] of this Court's Individual Rules" and noting that any further submission failing to "comply with the Court's Individual Rules … will be rejected"); *House v. Wackenhut Servs., Inc.*, 10-cv-9476 (CM) (FM), 2012 WL 4017334, at *2 (S.D.N.Y. Aug. 20, 2012) ("[The court] would have been well within [its] rights to strike plaintiff's memoranda for failure to comply with [its] guidelines.").

B. Leave to Amend

Pursuant to Federal Rule of Civil Procedure ("FRCP") 15(a)(2), a court should freely give leave to amend a complaint when justice so requires. This is a liberal standard, and "a motion to amend should be denied only if the moving party has unduly delayed or acted in bad faith, the opposing party will be unfairly prejudiced if leave is granted, or the proposed amendment is futile." *Agerbrink v. Model Service LLC*, 155 F. Supp. 3d 448, 452 (S.D.N.Y. 2016); *see also Ithaca Capital Investments I S.A. v. Trump Panama Hotel Management LLC*, 450 F. Supp. 3d 358, 369 (S.D.N.Y. 2020) ("The

Second Circuit has stated that a court should allow leave to amend a pleading unless the non-moving party can establish prejudice or bad faith.").

A district court has discretion to deny leave for "'good reason, including futility[.]'" *Holmes v. Grubman*, 568 F.3d 329, 334 (2d Cir. 2009) (quoting *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007)); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962); *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001). The Second Circuit has held that leave to amend may be denied based on futility when it is "beyond doubt that the plaintiff can prove no set of facts in support of [its] amended claims." *Pangburn v. Culbertson*, 200 F.3d 65, 71 (2d Cir. 1999) (internal quotation marks omitted). The party opposing the motion for leave to amend bears the burden of establishing the amendment's futility. *Ithaca Capital*, 450 F. Supp. 3d at 377.

To determine whether a proposed pleading is futile, courts analyze whether it would withstand a motion to dismiss pursuant to FRCP 12(b)(6). *Agerbrink*, 155 F. Supp. 3d at 456. "To survive a motion to dismiss, a 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 *Bell Atantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "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.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant had acted unlawfully." *Id.*

III. DISCUSSION

A. Motion to Strike

Celgene requests that the Court strike Appendix A and Appendix B to Plaintiffs' reply brief. Doc. 182 at 2. Combined, the appendices comprise 11 additional pages that the Court did not authorize. Doc. 173 (authorizing Plaintiffs to submit a 15-page reply

brief instead of the allotted 10-page reply brief limit per Rule 2(B)(i) of this Court's individual practices).

It is within the Court's "inherent discretion to strike excessive pages," but the Court also holds "reciprocal discretion to waive page limits." *National Grid Corporation Services, LLC v. Brand Energy Servs., LLC*, No. 13-cv-1275 (DRH) (ARL), 2017 WL 1194499, at *10 n.7 (E.D.N.Y. Mar. 30, 2017); *see also Fogel v. Wal-Mart de Mexico SAB de CV*, No. 13-cv-2282 (KPF), 2017 WL 751155, at *18 (S.D.N.Y. Feb. 27, 2017), *aff'd sub nom. Fogel v. Vega*, 759 F. App'x 18 (2d Cir. 2018), *and aff'd sub nom. Fogel v. Vega*, 759 F. App'x 18 (2d Cir. 2018) ("The Court certainly has the authority to *strike exhibits and pages that are attached* to circumvent its page limits…") (emphasis added); *see also Perez v. United States Immigration & Customs Enforcement*, No. 19-cv-3154 (PGG) (JLC), 2020 WL 5362356, at *9 (S.D.N.Y. Sept. 8, 2020) (declining to strike summary judgment memorandum of law that exceeded the page limits set by the Court). The Court in *Perez* declined to strike the additional seven pages because it determined that the plaintiff did not file the excess pages in bad faith. *Perez*, No. 19-cv-3154 (PGG) (JLC), 2020 WL 5362356, at *9. However, other Courts have decided to strike additional pages from pleadings that would give one party "additional pages of argument," separate from a finding of bad faith. *Freeman*, 2024 WL 3634738, at *10.

1. Appendix A

Appendix A is a 10-page, single-spaced "[r]oad [m]ap" in chart form that purports to identify "the deficiencies noted in the Court's March 31, 2025 Order with the purchasers' new, responsive factual allegations." Doc. 174 at 9; *see* Doc. 174-1, Appendix A. In a letter to the Court, Plaintiffs characterize Appendix A as a "tool/heuristic" and note that they "twice offered to compromise…" with Defendants by removing Appendix B and keeping Appendix A. Doc. 179 at 1. Plaintiffs later elaborate that "Appendix A is a tool offered—in response to the defendants' arguments that no new

facts cured the earlier deficiencies—to further aid the Court in evaluating whether the proposed amendments are futile." Doc. 183 at 4.

The Court strikes Appendix A for two independent reasons.

First, the Court allowed Plaintiffs to file 5 additional pages, and Plaintiffs blatantly ignored the Court's order by filing 11 pages of appendices. *Emanuel v. Griffin*, No. 13-cv-1806 (JMF), 2015 WL 1379007, at *17 (S.D.N.Y. Mar. 25, 2015) (noting a party's "blatant effort[s] to circumvent the page limits set by the Court" could be a basis to "impose sanctions on Plaintiffs' counsel," but denying the motion to strike as moot since the Court had already granted opposing party's motions in their entity). Plaintiffs do not engage with this argument, but this reason alone suffices to strike Appendix A.

Second, as Defendants contend, Appendix A, rather than being a "tool/heuristic," could be classified as arguments that should have been in the body of the reply brief. Doc. 182 at 6. In fact, Plaintiffs reply brief references only "[s]ome highlights" from Appendix A, suggesting it is not a "tool" for understanding the reply brief, but a supplemental document containing arguments not contained within the brief itself. Doc. 174 at 9. Additionally, as Defendants argue, "[d]espite being styled as an attachment to Plaintiffs' reply brief, Appendix A does not mention or respond to Celgene's opposition brief." Doc. 182 at 6. Appendix A cites only to the Court's Order dismissing the FAC and to Plaintiffs' proposed SAC, so it appears to be further argument. *See* Doc. 174-1. Plaintiffs argue that Appendix A simply "references pages in the Court's earlier order as an anchor point." Doc. 183 at 4. But Courts in this district have stricken "additional pages of argument" that "violate the briefing limits set by the Court," even where those pages "simply draw from, recategorize, and reorganize portions of" the record. *Freeman*, 2024 WL 3634738, at *10 (noting that lengthy indices were "argument," and as such "egregiously violate[d] the briefing limits set by the Court.").

2. Appendix B

Appendix B is a single-spaced collection of 15 "[c]ases holding DPP[21] and EPPs[22] can have antitrust standing." Doc. 174-2, Appendix B. "In an effort to avoid a motion, [Plaintiffs had already] agreed to withdraw Appendix B," Doc. 179 at 1, and their response to Defendants' motion to strike contains one sole reference to Appendix B, which they say "contained a one-page string cite." Doc. 183 at 3.

Even if Plaintiff had not "agree[d] to withdraw Appendix B [or] inquir[ed] about a surreply,"[23] Appendix B suffers the same fate as Appendix A. Doc. 179 at 1. That is, it is improper because the Court did not allow Plaintiffs to file additional pages on top of the already-increased 15-page limit. Accordingly, Appendix B is hereby stricken from the record.

B. Leave to Amend

The Plaintiffs seek leave to amend to address the deficiencies the Court identified in the March 2025 Opinion. "[A] motion to amend should be denied only if the moving party has unduly delayed or acted in bad faith, the opposing party will be unfairly prejudiced if leave is granted, or the proposed amendment is futile." *Agerbrink*, 155 F. Supp. 3d at 452. For the reason set forth below, the motion is DENIED.

1. Undue Delay or Faith Bad

The Court declines to deny the Plaintiffs' motion on the basis of undue delay, as it finds no indication that the Plaintiffs acted in bad faith or that the Defendants are unduly prejudiced by the delay—nor do Defendants argue as much.

The Plaintiffs sought permission to move for leave to amend on April 3, 2025, just three days after the Court issued its opinion and order on the motion to dismiss. Doc. 153. *See Community Association Underwriters of America, Inc. v. Main Line Fire*

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[21] DPPs are direct purchaser plaintiffs. *See* Doc. 174-2.

[22] EPPs are end payer plaintiffs. *See* Doc. 174-2.

[23] Plaintiffs assert that they "would not oppose [a surreply]." Doc. 179 at 1. However, "Celgene does not seek leave for a surreply." Doc. 182 at 9.

Protection Corp., No. 18-cv-4273 (PMH) (JCM), 2020 WL 5089444, at *2–*3 (S.D.N.Y. Aug. 28, 2020) (finding no undue delay where plaintiff filed its motion to amend two months after it discovered new information).

2. Prejudice

The Court likewise declines to deny the Plaintiffs' motion on the basis of undue prejudice. The Plaintiffs argue that the "SAC will not unduly prejudice the defendants" because the case remains at the pleading stage, Defendants would not be required to expend significant resources at this juncture since there has been no discovery and there is no trial date, the "SAC does not add entirely new or separate claims," and the amendments will not delay the resolution of this dispute. Doc. 164 at 9–11. The Defendants do not argue otherwise.

3. Futility

The Second Circuit has held that leave to amend may be denied based on futility when it is "beyond doubt that the plaintiff can prove no set of facts in support of [its] amended claims." *Pangburn*, 200 F.3d at 71 (internal quotation marks omitted). The non-moving party bears the burden of establishing the amendment's futility. *Ithaca Capital*, 450 F. Supp. 3d at 377.

To determine whether a proposed pleading is futile, courts analyze whether it would withstand a motion to dismiss pursuant to FRCP 12(b)(6). *Agerbrink,* 155 F. Supp. 3d at 456. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible "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.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant ha[d] acted unlawfully." *Id.* However, this "flexible plausibility standard" is not a heightened pleading standard, *In re Elevator Antitrust Litigation*, 502 F.3d 47, 50

n.3 (2d Cir. 2007) (quotation omitted), and "a complaint ... does not need detailed factual allegations" to survive a motion to dismiss, *Twombly*, 550 U.S. at 555.

The question on a motion to dismiss "is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Sikhs for Justice v. Nath*, 893 F. Supp. 2d 598, 615 (S.D.N. Y 2012) (quoting *Village Pond, Inc. v. Town of Darien*, 56 F.3d 375, 378 (2d Cir. 1995)). "[T]he purpose of Federal Rule of Civil Procedure 12(b)(6) is to test, in a streamlined fashion, the formal sufficiency of the plaintiff's statement of a claim for relief without resolving a contest regarding its substantive merits" or "weigh[ing] the evidence that might be offered to support it." *Halebian v. Berv*, 644 F.3d 122, 130 (2d Cir. 2011) (internal quotation marks and citations omitted). Thus, when ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts all factual allegations in the complaint as true and draws all reasonable inferences in the plaintiff's favor. *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014). Accordingly, when considering a motion to amend a pleading, a "court must accept as true all well-pleaded facts and draw all reasonable inferences in the moving party's favor." *Agerbrink*, 155 F. Supp. 3d at 456.

a. Walker Process Deficiencies

Plaintiffs allege that the "proposed SAC amendments clarify and further strengthen the allegations originally presented in the FAC, remedying the deficiencies identified by the Court regarding antitrust standing, as well as the plaintiffs' fraud on the PTO, sham litigation, and reverse payment allegations." Doc. 164 at 13. Defendants argue otherwise.

i. Antitrust Standing

"It is a well-established principle that, while the United States is authorized to sue anyone violating the federal antitrust laws, a private plaintiff must demonstrate 'standing.'" *Daniel v. American Board of Emergency Medicine*, 428 F.3d 408, 436 (2d Cir. 2005); *see Paycom Billing Services, Inc. v. Mastercard International, Inc.*, 467 F.3d

283, 290 (2d Cir. 2006) (in addition to demonstrating Article III standing, an antitrust plaintiff must also establish antitrust standing). The Second Circuit has explained that "[a]ntitrust standing is a threshold, pleading-stage inquiry" and that "when a complaint by its terms fails to establish this requirement we must dismiss it as a matter of law." *Gatt Communications, Inc. v. PMC Associates, L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (quoting *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 450 (6th Cir. 2007) (en banc)). This requirement "prevents private plaintiffs from recovering damages under" the Clayton Act "merely by showing injury causally linked to an illegal presence in the market." *Id.* at 76 (internal quotation marks and alteration omitted).

Plaintiffs allege that the SAC addresses the factors that courts consider when determining whether Plaintiffs have standing to bring the *Walker Process* fraud claims.[24] Doc. 164 at 13. *First*, the SAC explains that "(i) drug wholesalers are increasingly unlikely to bring antitrust class actions on behalf of direct purchasers; (ii) wholesalers are especially unlikely to do so with respect to specialty pharmaceuticals; and (iii) wholesalers rarely seek to enforce state antitrust laws." ¶ 78. They ague that "the combination of these factors significantly decreases the likelihood that direct drug purchasers will sue drug manufacturers to vindicate antitrust violations—especially where the higher drug prices that the antitrust violations enable mainly harm end payers (consumers and health insurers)." ¶ 85. *Second*, Plaintiffs argue that "several features of the pharmaceutical industry and generic entry render would-be generic competitors inefficient enforcers of antitrust laws, particularly with respect to *Walker Process* fraud allegations." ¶ 86. They argue, *inter alia*, that: (1) competitors in these types of actions have less of a financial incentive to bring such lawsuits (based on their lower potential

[24] These factors include: "(1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries." *In re DDAVP Indirect Purchaser Antitrust Litigation*, 585 F.3d 677, 688 (2d Cir. 2009).

damages recoveries) than the purchasers of these drugs; (2) competitor challenges to brand company patents often prioritize attacks on the patent(s) based on lack of infringement rather than unenforceability; and (3) that under the particular facts of this case the would-be generic competitors are not efficient enforcers of either federal or state antitrust laws, as evidenced by the fact that no would-be competitor to Celgene for pomalidomide has sought to enforce the antitrust laws thus far. ¶¶ 87–93. On the other hand, Plaintiffs argue that, *inter alia*, end-payers (1) are the last stop in the drug payment chain and therefore bear the full burden of illegal overcharges; (2) typically maintain no direct product supply arrangements with drug manufacturers and therefore face none of the commercial constraints that inhibit direct purchasers from pursuing litigation; and are often motivated to address restraints of trade that impact important medications given the drugs' medical importance to themselves or their members. ¶¶ 95–101.

In short, Plaintiffs argue that the "amendments show why the plaintiffs (end-payers) are the most 'efficient enforcers' of antitrust laws, why their injuries are not 'too remote,' why intermediaries do not create 'accompanying uncertainty' or require 'speculation' by the Court, and how the benefits to the proposed Class clearly outweigh any purported manageability issues." Doc. 164 at 13 (citing ¶¶ 77–103).

Defendants, on the other hand, contend that Plaintiffs' efforts to address the shortcomings via amendments to the complaint fail for four reasons: (1) Plaintiffs previously neglected to address the *In re DDAVP*, 585 F.3d at 688 (2d Cir. 2009) factors, thus waiving that legal issue, and the SAC does not contain any new factual allegations on standing; (2) the fact that Cigna and CenterWell (the "Direct Purchasers") are pursuing these same claims, diminishes the need to allow "a more remote party [such as the Plaintiffs]. . . to perform the office of a private attorney general"; (3) the SAC "does not remedy the remote nature of the injuries, the presence of intermediaries and intervening factors, or manageability issues"; and (4) Plaintiffs' "arguments that they are better

situated to certify a class, to bring state-law claims, or to recover more in damages … are irrelevant." Doc. 169 at 9–10.

The Court determines that Plaintiffs lack antitrust standing to bring *Walker Process* claims. The Court focuses on three primary factors in reaching this conclusion. First, the fact that the Direct Purchasers—"plaintiffs who are better situated to vindicate the antitrust laws"—exist "diminishes the justification for allowing a more remote party ... to perform the office of a private attorney general." *In re American Express Anti-Steering Rules Antitrust Litigation*, 19 F.4th 127, 141 (2d Cir. 2021). Second, Plaintiffs concede that they (i) "typically maintain no direct product supply arrangements with [Celgene]," ¶ 97; (ii) are the "last stop in the drug payment chain," ¶ 95; and (iii) are separated from Celgene by wholesalers and specialty pharmacies, ¶ 101. Accordingly, as Defendants note, Plaintiffs "rely entirely on a theory of indirect injury, having reimbursed unspecified individuals or entities who paid pharmacies that purchased Pomalyst from Celgene." Doc. 169 at 10. Third, standing hinges not on who is able to certify the broadest class action, but whether there are more efficient enforcers have the "self-interest [to] motivate [it] to vindicate the public interest in antitrust enforcement." *IQ Dental Supply, Inc. v. Henry Schein, Inc.*, 924 F.3d 57, 66 (2d Cir. 2019). As Defendants argue "both direct purchasers and generic competitors are well able to bring *Walker Process* claims (and Direct Purchasers in fact have done so)." Doc. 169 at 10.

Since the Court determines that Plaintiffs lack antitrust standing to bring *Walker Process* claims, it need not reach the parties' arguments based on the merits.

The '262 Patent

However, even if Plaintiffs had antitrust standing, Plaintiffs have failed to plausibly plead that the patents were obtained by fraud. Plaintiffs' allegations regarding the '262 patent once again fail because they do not plausibly plead materiality of the alleged omissions or false representations.

Defendants argue that, independently of standing, the Court should deny leave to amend as to the *Walker Process* claims because they fail to identify "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO," required by Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). Defendants argue that Plaintiffs have failed to plead how Celgene's alleged misrepresentations or omissions are material to the issued claims as to the '262 patent. Doc. 169 at 11. Plaintiffs on the other hand contend that the "SAC adds substantial detail as to how Celgene deliberately withheld crucial information from the PTO and made false and misleading statements about the prior art, upon which the examiner justifiably relied in allowing the '262 patent to issue." Doc. 164 at 14.

Plaintiffs note that the SAC includes additional allegations about Defendants' omission of "prior art that, if disclosed, would have prevented the issuance of the '262 patent." Doc. 164 at 14. For example, they assert that the new allegations in the SAC show that Defendants failed to disclose that D'Amato, another inventor, had already been allowed a patent for his claim that pomalidomide treated multiple myeloma by "late 2011/early 2012 … [when] Celgene, Zeldis, and Insogna had firmly led the examiner to believe Celgene and its scientists" had invented the first pomalidomide to treat multiple myeloma. Doc. 164 at 14. The SAC includes allegations that Celgene "concealed" and "deliberately omitted" from the PTO that the PTO had allowed D'Amato's '539 patent application before Celgene abandoned the application. ¶¶ 236–37; *see also* ¶¶ 221, 234–39. Specifically, "the only mention of D'Amato (2001) during the nearly 4-year patent prosecution was in the [initial list of nearly 300 references] … referring to pomalidomide as '3-aminothalidomide.'" Doc. 164 at 15 (referencing ¶ 242). According to Plaintiffs, the SAC also includes "additional specificity regarding the who, what, when, where, and how of the fraudulent statements and material omissions." Doc. 164 at 14. Defendants argue that "Celgene disclosed to the PTO no less than fifteen D'Amato patents and applications, including the '539 application." Doc. 169 at 12. The Court finds that, even

though the D'Amato patent was listed among nearly 300 references, Celgene did disclose the patent and, accordingly, did not deliberately conceal information from the PTO "if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner." *Fiskars, Inc. v. Hunt Manufacturing Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000). Additionally, "[o]nce the patent examiner became aware of the reference," Celgene had no "obligation to emphasize its importance." *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 749 F. Supp. 2d 892, 904 (W.D. Wisc. 2010).

Plaintiffs further allege that the SAC includes details about Defendants' "systematic attempts to dismantle D'Amato's patent portfolio" and to block said patents from issuing to D'Amato. Doc. 164 at 14. Specifically, the SAC alleges that "Celgene, along with co-conspirators Insogna and Zeldis … engaged in a misdirection, arguing that two other patents, the '230 and '554, did not teach the use of pomalidomide to treat cancer," therefore "conceal[ing] that the patent that had been allowed to D'Amato (the '539 patent application) and D'Amato 2001 *did* specifically teach the use of pomalidomide to treat multiple myeloma." ¶ 236 (emphasis in original). Plaintiffs argue that if the patent examiner had known about the prior art, the patent application would not have been allowed. ¶ 243.

Defendants respond that Plaintiffs do not explain "how any such disclosure would have been material, *i.e.*, would have stopped the '262 patent from issuing, particularly where disclosure of the '539 application, and 14 other D'Amato references, did not prevent issuance." Doc. 169 at 13. Given that, as stated above, Celgene did disclose the D'Amato references and the '262 patent still issued, the Court finds that Plaintiffs' argument is without merit.

None of Plaintiff's remaining allegations regarding the '262 patent suffice to adequately plead *Walker Process* fraud in securing the patent. Plaintiffs assert that the SAC also includes details to cure deficiencies that the Court previously identified as they relate to the allegation that Celgene and its agents made "misleading statements and

material omissions suggesting that the use of one thalidomide compound over another had not been publicly disclosed previously." Doc. 155 at 43 (finding this statement did not provide the specificity required by Rule 9(b)). The SAC notes that Celgene falsely asserted that "Davies does not teach or suggest that pomalidomide is more effective than thalidomide in the treatment of multiple myeloma. There would be no basis in Davies to select one compound over the other," ¶ 248, though David Stirling and Bruce Collins, Celgene's agents, had previously disclosed the superior potency of pomalidomide. Doc. 164 at 15. However, as Defendants note, this argument is insufficient to support a *Walker Process* fraud claim, as Celgene was simply making an argument that "Davies does not as a matter of law provide any relevant information to a [person of ordinary skill in the art]." Doc 169 at 16.

Plaintiffs also include allegations that Celgene misrepresented pomalidomide's unexpected results "regarding treatment for refractory patients," claiming that "[t]hese publications[25] clearly demonstrate unexpected results of the claimed therapy for relapsed or refractory multiple myeloma," because "[t]he prior art, including Schey (June 2002), specifically taught pomalidomide for the treatment of relapsed and refractory multiple myeloma." ¶ 251. However, since Celgene disclosed Schey (June 2002), *see* ¶ 174, "there is no conceivable basis for a fraud claim." Doc. 169 at 17.

Accordingly, Plaintiffs have not plausibly plead *Walker Process* fraud in procuring the '262 patent.

ii. The '428 and '3939 Patents

Plaintiffs' allegations regarding the '428 and '3939 patents are likewise insufficient to support a *Walker Process* fraud claim. Plaintiffs allege that their "more particularized allegations regarding the '262 patent also provide additional support for the

[25] Celgene's reference to "[t]hese publications" was to: "Schey et al., Expert Opinion, 2011" and "Lacy et al., Blood, 2011." ECF 112-5 at 54-55 (Dec. 20, 2011 Statement). Doc. 169 at 17. The SAC alleges that these publications "demonstrate[d] unexpected results of the claimed therapy for relapsed or refractory multiple myeloma." ¶ 251

plaintiffs' allegations that the follow-on method of treatment patents in the same family (the '428 and '3939 patents) were also obtained by fraud." Doc. 164 at 16.

First, as previously stated in the March 2025 Opinion, for the reasons set forth above regarding the '262 patent, Plaintiffs' catch-all claims regarding the "same fraudulent representations and omissions" in the prosecution of the '428 and '3939 patents also fail." Doc. 155 at 44. As Defendants note, Plaintiffs may not use a motion for leave to amend as a motion for reconsideration. Doc. 169 at 18 (citing *State Farm Mutual Automobile Insurance Co. v. Mallela*, No. cv-00-4923 (CPS), 2002 WL 31946762, at *14 (E.D.N.Y. Nov. 21, 2002)).

Second, Plaintiffs allege that the Thakurta Declaration falsely asserted that "[i]t has been surprisingly found that the resistance of multiple myeloma cells to pomalidomide and lenalidomide is not reciprocal … It is therefore my opinion that the results of the studies for treating relapsed and/or refractory multiple myeloma with single-agent pomalidomide would have been unexpected and surprising at the time the claimed invention was made." ¶ 298. Plaintiffs argue that Thakurta's statements were false because, at the time of the invention, it was known that thalidomide analogues were used for the treatment of relapsed/refractory disease and that pomalidomide could overcome drug resistance of multiple myeloma. Doc. 164 at 16–17. Plaintiffs also allege that patent examiners ordinarily give weight to sworn expert declarations of this kind and understandably rely on the information contained therein when deciding whether to allow patents to issue. Doc. 164 at 17. However, as the Court previously stated in the March 2025 Opinion, this claim is not plausibly alleged because "[t]he examiner was free to reach [her] own opinion about whether such a discovery was in fact 'surprising' based on the prior art that was available to her before the patent issued." *United Food and Commercial Workers Unions and Employees Midwest Health Benefits Fund v. Novartis Pharmaceuticals Corp.*, 902 F.3d 1, 11 (1st Cir. 2018) (citation omitted). That "[t]he Manual for Patent Examining and Procedure (MPEP) instructs examiners to give

deference to such declarations," Doc. 174 at 10, does not detract from the fact that the examiner was still able to reach her own conclusions. Additionally, as Defendants argue, Celgene did disclose studies demonstrating that pomalidomide could treat thalidomide-resistant and relapsed/refractory multiple myeloma. *See generally* Doc. 109 at 47, n.17.

Plaintiffs further allege that "it was Celgene's and Thakurta's false statements and material omissions regarding unexpected results"—not alleged misstatements they purport to point out in Celgene's October 2013 submission—"that was the deciding factor in the PTO's decision to reverse the prior rejection and allow the '428 method of treatment patent." ¶ 305.

For the aforementioned reasons, Plaintiffs have not plausibly plead *Walker Process* fraud in procuring the '428 and '3939 patents.

iii. The '427 Patent

The proposed SAC likewise does not support a claim that Celgene committed fraud in the procurement of the '427 patent. The SAC alleges that Defendants submitted a sworn declaration by Tutino "to overcome the examiner's rejection mischaracterizes the data to deceive the examiner into believing something that is not true, i.e., that the instability of this compound would have been unknown in light of the prior art." Doc. 164 at 17.

Specifically, the SAC alleges that the Tutino Declaration included "data ostensibly supporting Celgene's assertion of patentability based on 'unexpected results,'" but failed to specify when the reported testing was conducted. ¶ 279. According to Plaintiffs, these results were not "unexpected" given that "Thalidomide is notoriously unstable due to hydrolysis." ¶ 279. Consequently, Plaintiffs argue that these allegedly misleading statements led the examiner to allow the '427 patent to issue, noting that the "applicant showed in a declaration that stability of pomalidomide in formulation comprising various excipients is not predictable. The prior art of record is silent with respect to stability of pomalidomide when combined with various excipients." ¶ 282 (emphasis omitted).

Plaintiffs, in their Reply, assert that "[w]ithout the declaration, the '427 patent would not have issued." Doc. 174 at 11. The SAC also includes additional arguments regarding the "consideration and weight a reasonable examiner would place on a sworn expert declaration about what the prior art taught," and consequently, that the examiner justifiably relied on the Tutino Declaration in allowing patent '427 to issue. Doc. 164 at 17

However, as Celgene asserts, the Court already rejected these arguments in the March 2025 Opinion. Doc. 169 at 21. Once again, the Court is not convinced that Tutino's declarations characterizing the results as "unexpected" and "surprising" amount to a misrepresentation before the PTO. The examiner was free to reach his own opinion based on the relevant prior art. *See United Food*, 902 F.3d at 11 (citing *Akzo N.V.*, 808 F.2d 1471, 1482 (Fed. Cir. 1986)). Plaintiffs have not remedied their allegations to meet the requirements of Rule 9(b).

Additionally, Plaintiffs reassert their allegation that Celgene's failure to cite prior art, including Schey (April 2002), constitutes fraud in the procurement of the '427 patent. ¶¶ 276–77; *see* FAC ¶¶ 210–18. The Court once again finds this argument deficient given that the SAC does not remedy the issue the Court previously identified: the SAC "does not allege the materiality of Schey (April 2002) to the issued patent." Doc. 155 at 46. Consequently, Plaintiffs fail to meet the Rule 9(b) requirements. Under Rule 9(b), allegations of fraud are deficient where, as here, "the pleading fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—*i.e.*, the 'what' and 'where' of the material omissions." *Exergen*, 575 F.3d at 1329. Additionally, as Defendants point out, Plaintiffs acknowledge that "the examiner *rejected* Celgene's application notwithstanding this representation." Doc. 169 at 20.

Accordingly, Plaintiffs have failed to meet the Rule 9(b) requirements as they relate to the procurement of the '427 patent.

iv. The '467 and '5939 Patents

Lastly, Plaintiffs allegations as to the '467 and '5939 patents fare no better. Plaintiffs allege that the SAC includes additional allegations pertaining to the alleged falsity of Celgene's and Tutino's claims that the results were "unexpected," as well as allegations regarding the PTO's reliance on the Tutino Declaration in issuing the '467 patent. Doc. 164 at 18. Lastly, the SAC includes additional allegations about how the '5939 patent was allowed to issue after Celgene filed a terminal disclaimer "truncating the end date to coincide with the end date of the earlier issued, fraudulently-obtained formulation patents." Doc. 164 at 18.

For the reasons explained above, the allegations regarding the Tutino Declaration are insufficient, and, accordingly, Plaintiffs have failed to state a *Walker Process* claim as to the '467 and '5939 patents.

b. Sham Litigation

Plaintiffs' have once again failed to plead sham litigation. Plaintiffs allege that "Celgene pursued the lawsuits against the generic ANDA filers 'not because it had any realistic expectation of success of the merits but rather as a way to use the litigation process as an anticompetitive weapon to delay generics from entering the pomalidomide market and extend Celgene's monopoly.'" Doc. 164 at 18 (quoting ¶ 331). They argue that these allegations support their claims that the patents above were obtained by fraud. Doc. 164 at 18. The Court, however, again cannot conclude that Celgene's infringement actions against the ANDA filers were objectionably baseless, such that "no reasonable litigant could realistically expect success on the merits." *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49, 60 (1993).

First, Plaintiffs add no allegations to justify intrusion upon, or a chilling of, Celgene's right to petition under the First Amendment, as the Court previously noted. *See* Doc. 155 at 49 (citing *Professional Real Estate*, 508 U.S. at 56; *see also BE&K Construction Co. v. N.L.R.B.*, 536 U.S. 516, 532 (2002)). And as Defendants argue,

"because Plaintiffs still do not plausibly plead any pay-for-delay claim, nothing in their amendment suggests that Celgene's patent lawsuits were not 'a reasonable effort at petitioning for redress and therefore not a sham.'" Doc. 169 at 22 (quoting *T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.*, 312 F.3d 90, 94 (2d Cir. 2002)).

Second, Plaintiffs argue that the additional allegations in the SAC prove the invalidity of all patents, which is an independent basis for finding sham. Doc. 164 at 18. Specifically, Plaintiffs argue that no patent holder in Celgene's position would believe that the method-of-treatment patents could be adjudicated as valid in view of D'Amato's '539 patent application, D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), and Schey (October 2002). *See* ¶¶ 263, 323–24, 334–335, 394. According to Plaintiffs, a "reasonable patent holder in Celgene's position would not have expected to prevail in infringement litigation because the crystal form patents would be found invalid for lack of enablement and indefiniteness." Doc. 164 at 19; *see also* ¶¶ 349–66.

However, as Defendants point out, Plaintiffs fail to identify a "clear-cut reason that [Celgene] should have been certain that its lawsuit[s] would fail" when they were filed. Doc. 169 at 21 (quoting *Louisiana Health Service & Indemnity Co. v. Janssen Biotech, Inc.*, No. 19-cv-14146 (KM) (ESK), 2021 WL 4988523, at *9 (D.N.J. Oct. 27, 2021)). Furthermore, patent law presumes that "the [e]xaminer did his duty and knew what claims he was allowing." *Al-Site Corp. v. VSI International, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999). Accordingly, since the sources were disclosed to the examiner and it is rare that a "patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation"—and Plaintiffs do not include facts to warrant a finding that this is one such rare case—Plaintiffs' sham litigation claim fails. *Tyco Healthcare Group LP v. Mutual Pharmaceutical Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014).

c. Reverse Payment Claims

The parties disagree as to whether the settlement agreements between Celgene and generic manufacturers are subject to antitrust scrutiny. Plaintiffs argue that Celgene monopolized the market by making "unlawful reverse payments that delayed generic Pomalyst competition in linked Revlimid and Pomalyst agreements." Doc. 164 at 19. Previously, the Court held that Plaintiffs failed to establish that "Pomalyst and Revlimid settlement agreements are related," Doc. 155 at 58, so Plaintiffs argue that the amendments in the SAC directly tie the pay to the delay. Doc. 164 at 19. Plaintiffs allege that "the Pomalyst Generics will cease to delay generic Pomalyst when they stop getting paid in generic Revlimid allocations (first quarter 2026)." Doc. 164 at 19. In other words, Plaintiffs argue that Pomalyst Generics will stop delaying the generic drug once they stop receiving the related payments during the first quarter of 2026.

The SAC includes allegations of reverse payments in the course of settling Revlimid patent litigations. Specifically, the SAC alleges that "eight litigating Pomalyst ANDA sponsors (Natco, Teva, Dr. Reddy's, Mylan, Apotex, Alvogen, Aurobindo, and Hetero) received large and unjustified reverse payments in their generic Revlimid patent settlement agreements." ¶ 481. These allegedly "large and unexplained payments," Doc. 164 at 19, are:

5. Natco/Allergan collaboration: Natco received ~$660 million and Teva received ~$770 million;
6. Mylan, Alvogen, Apotex: $400 million to each;
7. Dr. Reddy's: at least a $400 million (but likely an additional $800 million); and
8. Aurobindo and Hetero: $160 million (most likely $216-$259 million) each.

¶¶ 482–87. Plaintiffs allege that they were only recently able to confirm these allegations due to statements made by executives at different companies within the three months prior to the filing of the motion to amend. Doc. 164 at 20.

The SAC fails to address the deficiencies previously identified by the Court,[26] and instead focuses on the claim that reverse payments derived from patent settlements on *Revlimid* delayed the entry of generic *Pomalyst*, which Defendants argue is a "different medicine in a different market, protected by different patents litigated in separate cases." Doc. 169 at 24. Claims as to Revlimid were already dismissed by another Court in *In re Revlimid*, 2024 WL 2861865.

In any case, the Court finds that Plaintiffs fail to plead the requisite "linkage"—that is, tying the pay to the delay—to sustain their reverse payment claims. As Defendants note, "Plaintiffs must plead that a 'reverse payment' was made in the Revlimid settlements in exchange for an agreement to delay the entry date in the Pomalyst settlement." Doc. 169 at 24. Plaintiffs allege that the "mechanism for transferring the payment was structured to gradually deliver payment to the Pomalyst Generics between 2022 and January 31, 2026." Doc. 164 at 20 (citing ¶¶ 488–92). Specifically, Plaintiffs allege that the alleged reverse payments were transferred through "volume-limited license[s]"[27] allocating cash flows from 2022 to January 31, 2026. Doc. 164 at 20; *see also* ¶ 517. One such case, Plaintiffs argue, is Teva's agreement, which "provides a new annual quota in March of each year, until 2026, at which point Teva expects lenalidomide revenues to decrease substantially." Doc. 164 at 20 (internal quotation marks omitted).

According to Plaintiffs, "Celgene prices Pomalyst artificially higher than Revlimid to insulate its earlier-established Revlimid business from competition from Pomalyst, illustrating that (1) cheaper pomalidomide would competitively threaten large portions of Celgene/Bristol Myers's Revlimid revenue, and (2) Celgene/Bristol Myers

[26] In the March 2025 Opinion, the Court held that "Plaintiffs have proffered no plausible reason to suggest that Natco/Breckinridge, Aurobindo, or the other Pomalyst ANDA first filers who settled were at "risk" or how that risk would constitute a reverse payment from Celgene," Doc. 155 at 62, whether based on "contractual exclusivity," "simultaneously timed entry dates," or confidentiality, *id.* at 57–62.

[27] Volume-limited agreements cap a generic drug's sales for a specified time. ¶ 460.

were aware of this competitive dynamic and, via its reverse payment settlements, sought to insulate Revlimid both from competition from generic Revlimid and generic Pomalyst." Doc. 164 at 21–22. Plaintiffs contend that this "payment mechanism doubles as an enforcement mechanism for inducing delay and ensuring compliance with the delay in the market for generic Pomalyst." Doc. 164 at 20. In other words, if any of the Pomalyst generics launched prior to the agreed-upon January 31, 2026 date, "they would have eliminated large portions of the reverse payment by driving down the price and/or quantities of their allocated generic Revlimid sales." *Id.* at 21. Plaintiffs conclude that "the moment the Pomalyst Generics stop getting paid in allocated generic Revlimid profits (January 31, 2026), they stop delaying generic Pomalyst (first quarter of 2026)." *Id.* The SAC also alleges that Bristol-Meyers sought to delay generic Pomalyst when Revlimid was the most lucrative in order to maximize its profits beyond what would have been "legally allowed" pursuant to its patents. ¶¶ 498–507; *see also* Doc 164 at 22. According to Plaintiffs, the First-Filer Revlimid Generics (Natco, Teva, and Dr. Reddy's) had the strongest incentive to delay generic Pomalyst because they received the largest payments. Doc. 164 at 22 (citing ¶¶ 517–24).

These arguments fail for two reasons. *First*, as the Court in *In re Revlimid* held, volume-limited licenses in this scenario do not constitute "reverse payment within the meaning of *Actavis*." 2024 WL 2861865, at *64. The Court reaches the same conclusion here. *Second*, Plaintiffs' allegations fail to establish a linkage between Pomalyst and Revlimid agreements for several reasons, including that most of Plaintiffs new allegations pertain to generic Revlimid. ¶¶ 474–79. As the Court previously held when analyzing the FAC, the SAC likewise fails to identify references to or provision within any of the Pomalyst settlements mentioning Revlimid or any other plausible reason to believe that the Revlimid agreements were incorporated within them, or the reverse.

Plaintiff lastly alleges that these large payments were "unjustified" for many reasons, ¶¶ 528–46, including the "settlements with Natco, Teva, and Dr. Reddy's did not

reflect a compromise on the merits of the parties' substantive patent positions," ¶ 547. However, given that Plaintiffs have failed to plausibly allege an unlawful reverse payment, the Court does not consider whether the alleged payments were "large and unexplained," or otherwise "unjustified."

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to strike Appendix A and Appendix B is GRANTED. Plaintiffs' motion to for leave to amend is DENIED. The Clerk of Court is respectfully directed to terminate the motions, Docs. 162 and 181, and close the case.

The Clerk of the Court is also respectfully directed to terminate the motion, Doc. 16, in *CenterWell Pharmacy, Inc. v. Celgene Corporation et al*, 24-cv-06924 (ER).

It is SO ORDERED.

Dated: March 30, 2026
New York, New York

EDGARDO RAMOS, U.S.D.J.