UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ALLERGAN PLC SECURITIES LITIGATION

No. 18 Civ. 12089 (CM)(GWG)

DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

McMahon, J.:

Lead Plaintiff DeKalb County Pension Fund (hereinafter referred to as "DeKalb" or "Plaintiff") brings this securities fraud lawsuit on behalf of itself and a class of similarly situated purchasers of shares of Allergan – a global pharmaceutical company. Plaintiff accuses Defendants – Allergan PLC and associated individual defendants (collectively "Allergan") – of failing to disclose information about a potential link between one of the company's products, textured silicone-gel breast implants, and a rare form of cancer.

Presently before the Court are cross motions for summary judgment: one for summary judgment dismissing the complaint, filed by Defendant Allergan (Dkt. No. 347) and one for partial summary judgment on the issue of liability, filed by DeKalb (Dkt. No. 351). Also before the Court are five *Daubert* motions to exclude the opinions and proposed testimony of several experts.

For the reasons set forth below, Defendants' summary judgment motion is granted, Plaintiff's partial summary judgment motion is denied, and the complaint is dismissed. There is

no need to address in detail the parties' *Daubert* motions as the testimony of the parties' experts is not necessary to grant Allergan's motion. Those motions are, therefore, denied as moot.

BACKGROUND

The Court assumes the parties' familiarity with the facts and recounts only the facts relevant to this summary judgment decision.

A more extensive discussion about the background of this case is available in the Court's opinions and orders addressing Allergan's motion to dismiss and the motions for class certification. *See In re Allergan PLC Sec. Litig.* ("*Allergan I*"), No. 18 CIV. 12089 (CM), 2019 WL 4686445 (S.D.N.Y. Sept. 20, 2019) (granting in part and denying in part Defendants' motion to dismiss); *In re Allergan PLC Secs. Litig.* ("*Allergan II*"), No. 18 CIV. 12089 (CM)(GWG), 2020 WL 5796763 (S.D.N.Y. Sept. 29, 2020) (denying motion for class certification filed by the former lead plaintiff, Boston Retirement System); *In re Allergan PLC Sec. Litig. ("Allergan III")*, No. 18 CIV. 12089 (CM)(GWG), 2021 WL 4077942 (S.D.N.Y. Sept. 8, 2021) (granting DeKalb's motion for class certification).

I. Factual Background

A. The Parties

Lead Plaintiff DeKalb is a pension fund that alleges that it purchased shares of Allergan at artificially inflated prices between January 30, 2017 and December 19, 2018, inclusive (the "Class Period"). (Dkt. No. 58 ¶ 19). *See also Allergan III*, 2021 WL 4077942, at *1.

Defendants include Allergan and certain of its senior executives.

Allergan is a global pharmaceutical and medical products company engaged in the development, manufacturing, and distribution of over 100 pharmaceutical and medical-aesthetics

products. (Defs.' 56.1 ¶ 1).[1] The company's stock is publicly traded on the New York Stock Exchange. (Defs.' 56.1 Counter ¶ 3).

The Executive Defendants include Brenton L. Saunders, who was Allergan's President, chief executive officer ("CEO"), and Chairman of the Board during the Class Period (Defs' 56.1 ¶ 286); Maria Teresa Hilado, who served as Allergan's chief financial officer ("CFO") from December 2014 until February 2018 (*id.* ¶ 298); Matthew W. Walsh, Allergan's CFO from February 2018 through the end of the Class Period (*id.* ¶ 299); Frances DeSena, who was vice president of Allergan's U.S. Brand and Research and Development Communication division during the Class Period (*id.* ¶ 300); Mark Marmur, who was global media relations and executive communications director of Allergan from 2015 through 2018, and served as lead for international communications and public relations from 2018 through the end of the Class Period (*id.* ¶ 305); Paul Bisaro, who was a Director on Allergan's Board from December 2016 through August 2018 (*id.* ¶ 309); and William Meury, Allergan's chief commercial officer ("CCO") during the Class Period (*id.* ¶ 315).

B. Allergan's Textured Breast Implants and BIA-ALCL

For over thirty years, Allergan and its corporate predecessors – specifically, McGhan Medical Corporation ("McGhan"), which later changed its name to Inamed Corporation ("Inamed") before Allergan purchased substantially all of the company in March 2006 – have manufactured and sold breast implants for post-mastectomy reconstructive surgery and cosmetic augmentation. (Defs' 56.1 ¶¶ 13, 14).

[1] References to Defendants' Rule 56.1 Statement (Dkt. No. 361) are designated "Defs.' 56.1"; references to Defendants' Counter-Statement of Undisputed Material Facts (Dkt. No. 382) are designated "Defs.' 56.1 Counter"; references to Plaintiff's Rule 56.1 Statement (Dkt. No. 369) are designated "Pl.'s 56.1"; references to Plaintiff's Counter-Statement of Undisputed Material Facts (Dkt. No. 401) are designated "Pl.'s 56.1 Counter".

During the Class Period, Allergan sold breast implants with several different shell textures, including macro-textured breast implants bearing the "BIOCELL" trademark, micro-textured breast implants bearing the "MicroCell" trademark, and smooth breast implants, which were sold under several brand names. (Defs.' 56.1 ¶ 2).

Breast implants with textured shells have been reported to offer several important benefits over breast implants with smooth shells, including: better adherence to tissue; lower rates of movement due to their better adherence; lower rates of capsular contracture, which is a common, disfiguring and painful condition experienced by women with implants. Moreover, because of their lower rates of movement and capsular contracture, women who use textured breast implants need fewer re-operations. (Defs' 56.1 ¶¶ 23-35).

Allergan's textured implants specifically have advantages over other types of implants. As late as the end of September 2018, the chairman of the BIA-ALCL committee of France's National Agency for the Safety of Medicines & Health Products ("ANSM"), Dr. Christian Marinetti, issued a public statement in which she asserted that Allergan's Biocell implants were "essential" and "often irreplaceable" because they are "the only product that can adhere" to certain patients and because they "enable optimal restoration of the body image of patients after amputation," in contrast to "[o]ther implants [that] may prove to be too mobile" and "requir[e] repeat operations that have their own risks." (DSJ Ex. 123; Defs' 56.1 ¶ 200).

Anaplastic large cell lymphoma ("ALCL") is a form of non-Hodgkin lymphoma. (Pl.'s 56.1 ¶ 48). As long ago as 1997, studies suggested that the disease was associated with breast implants. (*Id.* ¶¶ 50-61). In 2016, the World Health Organization designated breast implant-associated anaplastic large-cell lymphoma ("BIA-ALCL") as a distinct subgroup of ALCL. (Pl. Ex. 127; Dkt. No. 424 ¶ 421). BIA-ALCL is rare and generally treatable. (Pl.'s 56.1 Counter ¶ 12).

As of February 6, 2019, the FDA had identified 457 reported cases of BIA-ALCL in the United States, and 9 reported deaths from the disease. (DSJ Ex. 54).

C. Scientific Studies and Regulatory Advisories on BIA-ALCL

Before and during the Class Period, studies analyzed reported cases of BIA-ALCL to understand more about the disease. Due to the rarity of BIA-ALCL and the preliminary nature of the studies, the authors invariably noted that there were many gaps in their data. Specifically researchers said that they lacked access to sales data by manufacturer and that implants were often not labeled by their manufacturer – as well as the fact that there were very few reported cases of the disease. (*See* Defs' 56.1 ¶¶ 49, 77; Dkt. No. 424 ¶ 551).

Plaintiff claims that, by the beginning of the Class Period in January 2017, studies had linked ALCL specifically to breast implants with a textured outer shell. (Dkt. No. 399 at 4). As long ago as 2011, the FDA issued a report detailing the agency's belief that "there is a possible association between breast implants and ALCL," and that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." (Pl.'s 56.1 ¶ 56). Obviously, this information was in the public domain long before the Class Period.

Plaintiff further alleges that, beginning in 2015, scientists began linking BIA-ALCL specifically to Allergan products, and that substantial evidence showed that Allergan's Biocell textured implants were associated with a higher rate of incidence of the disease than competitors' textured implants were. (Dkt. No. 399 at 4). Plaintiff cites the following studies as evidence:

- *The Gidengil Study*: In March 2015, a study published in the Plastic and Reconstructive Surgery journal reported 54 cases of BIA-ALCL in women with breast implants. 31 of those implants were of unknown manufacture. Of the 23 cases for which manufacturer information was known, 19 of the patients had Allergan implants, 3 had Nagor implants, and 1 had a Silimed implant. (DSJ Ex. 78; Pl.'s 56.1 Counter ¶ 417).

- *The Brody Study:* In March 2015, a study published in the Plastic and Reconstructive Surgery journal identified 173 cases of BIA-ALCL. The manufacturer of the implant could not be identified in 61 of those cases. Of the 127 cases where the manufacturer was known, 97 cases involved Allergan implants, 3 cases involved both Allergan and Mentor implants (i.e., the woman had received implants from both manufacturers), 3 cases involved only Mentor implants, 5 cases involved PIP implants, 3 cases involved Nagor implants, and 1 case involved a Sientra implant. (DSJ Ex. 33; Pl.'s 56.1 Counter ¶ 413).

- *Regulator Data:* In June 2016, the ANSM sent a letter to Allergan stating that, of the 29 cases of BIA-ALCL seen in France, 27 occurred in women who had Allergan implants. (Dkt. No. 399 at 5; Pl. Ex. 73; Pl.'s 56.1 Counter ¶ 487). In July 2016, the ANSM issued a public release reporting these finding. It noted that "In the 29 cases diagnosed to date in France, Allergan brand textured breast implants are currently over-represented," but went on to state that the "illness remains rare compared to the number of breast implants inserted each year." (DSJ Ex. 38, Defs' 56.2 ¶ 194-95). The ANSM further said in this release that it was "continu[ing] its investigations" of BIA-ALCL "for all brands of breast implants," and recommended continued monitoring of patients with implants, rather than removing any products from the market or changing their use. (Defs' 56.2 ¶ 196).

- *The Doren Study*: In May 2017, a study was published in the Plastic and Reconstructive Surgery journal. The study compared the rate of incidence of BIA-ALCL in patients who had textured implants manufactured by Mentor (Allergan's leading competitor during the Class Period) and in patients whose textured implants were manufactured by Allergan. Mentor uses a negative imprint stamping method to create its textured surface, while Allergan uses a salt-loss method for the same purpose. Of the 100 confirmed BIA-ALCL cases studied, 51 had a confirmed history of textured implants. Doren found that "[t]he overall incidence rate for salt-loss implants during this period was 1.87 per 1 million person-years. The overall incidence rate of breast implant–associated ALCL for negative-imprint stamping implants during this period was 0.33 per 1 million person-years. Compared to the salt-loss implants, the negative-imprint stamping implants were associated with a significantly lower incidence rate ($p < 0.001$)." (DSJ Ex. 36, Pl.'s 56.1 Counter ¶¶ 583-85).

- *The Loch-Wilkinson Study*: In May 2017, a study published in the Plastic and Reconstructive Surgery journal analyzing BIA-ALCL in Australia & New Zealand concluded that the risk of developing BIA-ALCL to be 14.11 times higher with Biocell textured implants and 10.84 higher with polyurethane (Silimed's) textured implants compared with Siltex (Mentor's) textured implants. (Dkt. No. 399 at 5; DSJ Ex. 74; Pl.'s 56.1 Counter ¶¶ 517, 520).

Like the earlier FDA report, all of these studies were published, so the information was reasonably available to investors during the Class Period – and specifically when the four statements alleged in this lawsuit to be misleading were made.

In addition, prior to and during the Class Period, Allergan was tracking and documenting its own case count of BIA-ALCL cases. In an internal Allergan presentation, Joseph Purpura, Head of Device Safety at Allergan, presented data showing that, as of December 31, 2016, Allergan had identified 376 confirmed and suspected cases of BIA-ALCL. Of these, 247 cases were associated with Allergan-brand implants, and Mentor (the manufacturer with the next-largest BIA-ALCL count) was associated with 32 cases; in 80 of the 376 cases the identity of the manufacturer was unknown. (Dkt. No. 399 at 6; Pl. Ex. 56; Pl.'s 56.1 Counter ¶¶ 550-51).

D. The ANSM Recall (The Alleged Corrective Disclosure)

In November 2018 – just two months after the Chair of its BIA-ALCL Committee had announced to the world that Allergan's Biocell textured implants were "essential" and "often irreplaceable" – the ANSM announced that its expert committee would meet in February 2019 to gain "a global perspective on the use of [breast] implants," after which it would "make a decision on the use of textured breast implants." (DSJ Ex. 125; Defs' 56.1 ¶ 202). Following this announcement, the French Minister of Health stated in an interview that the ANSM was not yet "prohibiting the fitting of textured implants" and acknowledged that "there are cases where it is better for women to have a textured implant, so if we ban them completely, we will put a number of women in difficulty." (DSJ Ex. 126; Defs' 56.1 ¶ 203).

Medical devices marketed in Europe bear a Conformité Européenne ("CE") mark, which connotes that they conform to European health and safety standards. Eligibility for the marks is determined periodically by the "GMED" – a European regulatory body responsible for assessing

and certifying the conformity of medical devices to European standards.[2] (Defs' 56.1 ¶¶ 216, 217). CE marks are typically valid for five years. (DSJ Ex. 132). Allergan's textured breast implants happened to be up for their 5-year renewal of their CE marks for use in France in December of 2018 – two months before the ANSM review of textured implants generally was scheduled to take place. (*Id.*) Allergan was the only manufacturer of textured implants whose CE mark was up for renewal in France before that conference. (Defs' 56.1 ¶ 214).

On December 14, 2018, the GMED opted not to reissue the CE mark for Allergan's textured implants. The GMED stated that the denial was based on (i) issues with the "technical file assessed to demonstrate the conformity of the product to requirements of the [EU] directive"; and (ii) "review of the post marketing data of the textured implants which raised a specific concern on ALCL," – specifically, that, "information provided in the file does not demonstrate that the benefit/risk ratio is equivalent or greater than alternative solutions *such as smooth breast implants*." (Defs.' 56.1 ¶ 217) (emphasis added). The GMED said nothing about the relative risk/benefit ratio for different manufacturers of textured implants.[3]

Because medical devices that lack a CE mark cannot be sold in Europe, four days later, on December 18, 2018, ANSM ordered a recall (hereinafter the "ANSM Recall") of textured breast implants manufactured by Allergan from the European market. (Defs' 56.1 ¶ 220). The ANSM announcement noted that it had "not as yet identified any immediate health risk to women carrying

[2] CE marks are required to sell a wide variety of products in the EU, and signify that the products meet certain requirements. CE marks are renewed at regular intervals and issued by "notified bodies" rather than the primary health regulators in EU member states. *See* European Commission, CE Marking (last visited Dec. 12, 2022), https://single-market-economy.ec.europa.eu/single-market/ce-marking_en. For example, in France, the notified body is GMED, whereas the primary health regulator is the ANSM.

[3] As far as the court knows, none the few cases of BIA-ALCL that have been reported are in women who have so-called "smooth breast implants." This case is not about the relative safety of smooth versus textured implants; it is about whether Allergan failed to disclose that its textured implants were more closely associated with the disease than were the textured implants of other manufacturers.

the implants concerned" but stated that "it recommended health professionals *to prefer the use of breast implants with a smooth envelope, pending the opinion of a committee of experts on the use of implants"* and that it would "make a decision on the use of textured-envelope breast implants" after its February 2019 meetings. (*Id.* ¶¶ 225-26) (emphasis added). Again, there was no mention by the ANSM of relative rates of BIA-ALCL for different manufacturers of textured implants.

In April 2019, ANSM decided to recall all heavily textured implants from the European market, regardless of manufacturers. (Defs' 56.1 ¶¶ 230, 234-35).

II. Procedural Background

Following the December 2018 ANSM Recall announcement, Allergan's common stock price fell $10.20, or nearly 7%, to close at $136.56 on December 19, 2018. (Pl.'s 56.1 ¶ 142).

This case was filed on December 20, 2018. (Dkt. No. 1).

The Court originally appointed Boston Retirement Services ("BRS") to serve as lead plaintiff and it filed the Consolidated Amended Class Action Complaint ("CAC") – the operative complaint in this action – alleging two counts against Allergan and seven individual defendants affiliated with Allergan for (1) violations of Section 10(b) of the Exchange Act and the corresponding SEC Rule 10b-5 against all defendants; and (2) violations of Section 20(a) of the Exchange Act against the individual defendants. (Dkt. No. 58). Plaintiff alleged that Allergan was well aware of the studies that showed a higher incidence of BIA-ALCL in patients with Allergan's textured breast implants than those made by others, but nonetheless issued statements that downplayed the fact that patients had a higher risk of developing BIA-ALCL if they used Allergan's textured implants. (Dkt. No. 58 ¶¶ 78, 94, 161). And they alleged that the revelation of Allergan's closer association with BIA-ALCL led to the sudden drop in stock price following the ANSM Recall, and caused damages to the putative class of investors, violating Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. (Dkt. No. 58 ¶¶ 12-14).

Following Allergan's motion to dismiss, very little was left of the CAC. The court allowed Plaintiff to go forward only on the theory that four specifically identified statements "gave investors a false impression that Allergan's implants were no more linked with BIA-ALCL than other implants" manufactured by other companies. *Allergan I*, 2019 WL 4686445, at *25.

The parties proceeded with discovery. During discovery, the Court denied BRS' motion for class certification for the reasons set forth in *Allergan II*, 2020 WL 5796763. The Court granted DeKalb's motion for class certification as the new Lead Plaintiff in *Allergan III*, 2021 WL 4077942.

LEGAL STANDARD

Summary judgment is appropriate only where "there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is "material" "if it might affect the outcome of the suit under the governing law." *Frost v. N.Y.C. Police Dep't*, 980 F.3d 231, 242 (2d Cir. 2020). The relevant inquiry on application for summary judgment is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52.

A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. *Westinghouse Elec. Corp. v. N.Y.C. Transit Auth.*, 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there will be no *genuine* issue of *material* fact." *Anderson*, 477 U.S. at 247-48 (emphasis in original). "Uncertainty as to the true state of any material fact

defeats the motion." *U.S. v. One Tintoretto Painting Entitled The Holy Fam. With Saint Catherine & Honored Donor*, 691 F.2d 603, 606 (2d Cir. 1982).

The movant bears the initial burden of demonstrating the absence of a genuine dispute of material fact. Fed. R. Civ. P. 56(c)(1). "Courts must construe the evidence and draw all reasonable inferences in the non-moving party's favor." *United Specialty Ins. Co. v. JD Com. Builders Inc.*, No. 18-cv-6735 (CM), 2020 WL 49017661, at *3 (S.D.N.Y. Aug. 20, 2020).

DISCUSSION

I. Defendants Are Entitled to Summary Judgment Dismissing Plaintiff's Section 10(b) Claim

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5, which implements the statute, prohibits making "any untrue statement of a material fact or [omitting] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To recover for a violation of Section 10(b) and Rule 10b-5, a private securities plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.*, 129 F. Supp. 3d 48, 65 (S.D.N.Y. 2015) (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014)).

For the reasons outlined below, Plaintiff has not produced sufficient evidence to show that a genuine issue of material fact remains on the elements of (i) a misrepresentation or

omission (falsity); (ii) materiality; and (ii) loss causation.[4] Thus, Defendant's motion for summary judgment on the Section 10(b) claims is granted and Plaintiff's motion for partial summary judgment is denied.

A. There is No Evidence That Allergan Made a False or Misleading Statement or Omission

To prove a material misrepresentation or omission, a plaintiff must show that the defendant either made an untrue statement of a material fact or omitted to state a material fact necessary to make whatever statements it made not misleading. 17 C.F.R. § 240.10b-5(b).

"A violation of Section 10(b) and Rule 10b-5 premised on misstatements cannot occur unless an alleged material misstatement was false *at the time it was made*." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), *aff'd*, 604 Fed. App'x. 62 (2d Cir. 2015) (emphasis in original) (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 812–13 (2d Cir. 1996)). A statement believed to be true when made, but later shown to be false, is insufficient, because it lacks contemporaneous falsity. *Id.* (citing *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)). "[F]alsity is a failure to be truthful – it is not a misapprehension, misunderstanding, or mistake of fact at the time a statement was made." *San Leandro,* 75 F.3d at 813. Moreover, a plaintiff "must do more than simply assert that a statement is false – [it] must demonstrate with specificity why that is so." *Lululemon*, 14 F. Supp. 3d at 571 (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)).

Similar to the falsity of statements, omissions are only actionable if a defendant is under a duty to disclose and fails to do so. *Levitt v. J.P. Morgan Sec., Inc.*, 710 F.3d 454, 465 (2d Cir. 2013). Such a duty to disclose arises where a "statute or regulation requir[es] disclosure" or a

[4] Because there are more obvious bases for dismissing this claim, there is no need to address Defendants' arguments about lack of scienter. To forestall argument on the point, no one should read anything substantive into my decision not to address this issue.

corporate statement would otherwise be "inaccurate, incomplete, or misleading." *Stratte–McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015) (quoting *Glazer v. Formica Corp.*, 964 F.2d 149, 157 (2d Cir. 1992). "Silence, absent a duty to disclose, is not misleading under Rule 10b-5." *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988); *see also In re Time Warner Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993).

1. None of the Four Alleged Misstatements Was Literally False or Misleading

Plaintiff alleges that Allergan made four statements during the Class Period that were false and misleading. (Dkt. No. 399 at 9). However, Plaintiff has produced no evidence showing that any of these statements included a literally untrue statement of material fact or were otherwise misleading.

a. Alleged Misstatement 1: ABC News 7 January 2017 Response

The first alleged misstatement is a statement that Mark Marmur – Allergan's global media relations and executive communications director – submitted in response to a January 30, 2017 *ABC News 7* article titled, "Woman who beat cancer once says breast implants caused cancer again." (Pl.'s 56.1 Counter ¶ 423). The statement reads:

> "According to the FDA, BIA-ALCL has been reported in patients with textured breast implants from all manufacturers."

(Dkt. No. 399 at 14).

Plaintiff has not produced any evidence to suggest that this statement is literally false. Instead, Plaintiff asserts that the FDA's database reflected a large overrepresentation of BIA-ALCL cases associated with the use of Allergan's textured implants, and that studies showed a higher incidence rate for BIA-ALCL with Allergan implants as opposed to those of other manufacturers. This, according to Plaintiff, created a duty to disclose that, according to the FDA, there was a "stronger association" between Allergan's textured implants and BIA-ALCL as

compared to other manufacturers. (Dkt. No. 399 at 14). Absent that, according to Plaintiff, Allergan's statement, while technically true, was misleading.

But Plaintiff is incorrect when it asserts that Allergan had a "duty" to disclose information about comparative incidence rates among various manufacturers of textured breast implants. Allergan's statement mentioned nothing about the relative safety of its implants and did not compare its products to those of any other manufacturer of textured breast implants. "It is well settled that a corporation is not required to reveal all facts on a subject just because it reveals a single fact." *In re Rockwell Med., Inc. Sec. Litig.*, 2018 WL 1725553, at *10 (S.D.N.Y. Mar. 30, 2018). Moreover, the studies that, according to Plaintiff, showed a higher rate of incidence of BIA-ALCL in patients with Allergan implants were not a secret; they were publicly available, so that information was part of the "total mix" of information available to investors at the time the statement was made.

b. Alleged Misstatement 2: May 2018 Allergan Press Release

The second alleged misstatement is contained in a press release Allergan issued on May 29, 2018 entitled, "Allergan Responds to Media Reports on Breast Implant Associated Anaplastic Cell Lymphoma (BIA-ALCL)." (Pl.'s 56.1 Counter ¶ 434). Plaintiff alleges that the following language was false and misleading:

> "The safety profile of Allergan's smooth and textured breast implants is supported by . . . more than a decade of U.S. and European clinical experience . . . as well as a large number of peer-reviewed and published studies," and that "BIA-ALCL has been reported with multiple different implant manufacturers."

(Dkt. No. 399 at 15).

Again, Plaintiff has not produced any evidence tending to show that what Allergan said was literally false. Again, Plaintiff asserts that Allergan failed to disclose the alleged fact that its implants were associated with more cases of BIA-ALCL than were other manufacturers' implants.

But once again, Allergan's statement is not comparative in nature; it simply says that BIA-ALCL has been reported with multiple different manufacturers' implants. Per scientific and regulatory reporting, that is true. (*See e.g.*, Pl.'s 56.1 Counter ¶ 195; DSJ Ex. 36 at 1049). Allergan thus had no duty to disclose in this statement information about relative incidence rates of BIA-ALCL – information that, to the limited extent it had been studied, was publicly available.

Plaintiff also points to no evidence that Allergan's "smooth and textured implants" had not been used safely for over a decade in the U.S. and Europe. Indeed, at the time the statement was made, Allergan's implants were FDA approved and bore the CE safety mark in Europe. Its implants had been used in hundreds of thousands of women, with few reported cases of BIA-ALCL and fewer than 10 deaths, not all of which involved Allergan products. Even at the end of 2018, the chairman of the ANSM's BIA-ALCL committee stated that Allergan's Biocell implants were "essential" and "often irreplaceable" because they are "the only product that can adhere" to certain patients, in contrast to "[o]ther implants . . . requir[ing] repeat operations that have their own risks." (DSJ Ex. 123; Defs' 56.1 ¶ 200). Nor has plaintiff demonstrated that there are not in fact a large number of peer-reviewed and published studies supporting the safety profile of Allergan's products.

c. Alleged Misstatements 3 and 4: Allergan's 2016 and 2017 10-Ks

The final Allergan statements that Plaintiff alleges are false and misleading are identical statements included in (i) Allergan's Form 10-K for the year ended December 31, 2016, which was filed by Allergan on February 24, 2017; and (ii) Allergan's Form 10-K for the year ended December 31, 2017, which was filed by Allergan on February 16, 2018. The statements read:

> "From time to time reports related to the quality and safety of breast implant devices are published, including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants, as well as negative reports from regulatory

authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company."

(Dkt. No. 399 at 12).

Plaintiff does not allege that the first part of this statement, "From time to time reports related to the quality and safety of breast implant decides are published, including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants," is either untrue or misleading. Rather, Plaintiff claims that the final clause of this statement, "as well as negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company," could be interpreted by a reasonable investor as stating that another manufacturer of textured implants was more closely associated with BIA-ALCL than Allergan. (*Id.* at 13).

This argument is utterly devoid of merit.

Relying entirely on "could haves," Plaintiff has not identified a single investor who actually interpreted this phrase in the manner Plaintiff alleges it "could be" interpreted. That is probably because Plaintiff is constrained to agree (and in fact does agree) that this statement does not refer to any purported association between textured breast implants and BIA-ALCL, let alone to the relative rate of incidence of BIA-ALCL in the products of various manufacturers. In its own Counter Statement of Undisputed Facts, Plaintiff agrees that the second clause references a wholly unrelated scandal involving the safety of implants made by the French breast implant manufacturer, Poly Implant Prothèse ("PIP"). (Pl.'s 56.1 Counter ¶ 268). In 2010, it was discovered that PIP used industrial-grade silicone in its breast implants, leading to significant harm to women whose implants ruptured. This led to a product recall (because of the defective silicone, not the texture of the implants), lawsuits, investigations, PIP's bankruptcy, criminal charges

against PIP's CEO, and the replacement of the French health regulator. (Defs' 56.1 ¶¶ 271-274). Allergan had nothing to do with any of this.

One might wonder why Allergan would refer to this event in 10-Ks filed many years after the scandal broke. The answer is simple: the sheer magnitude of the PIP scandal – involving over 300,000 defectively manufactured implants – and its impact on the breast implant industry led to years of news coverage of these events. (*Id.* ¶ 270). Public reports continued to be released about the PIP scandal, including during the Class Period, (*see, e.g.*, DSJ Exs. 150-51), and afterward. (*See, e.g.*, DSJ Ex. 252). The statement in Allergan's 10-K concerns adverse publicity about the quality and safety of breast implants; the PIP scandal unquestionably led to years of adverse publicity about the quality and safety of breast implants, and the fact that it continued to be newsworthy during and after the Class Period makes a reference to it in Allergan's discussion of the subject perfectly understandable.

Not only does the cited clause not refer to BIA-ALCL, but it is phrased in such a way as to make it clear to the reader that it concerns another subject. In its 10-Ks, Allergan identifies two separate examples of "reports related to the quality and safety of breast implant devices:" (1) "reports that have suggested a possible association between [ALCL] and breast implants," and (2) "negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company." The second example is preceded by the words "as well as," which (as both sides agree) means "in addition to." (Pl.'s 56.1 Counter ¶¶ 276-77). The use of that phrase suggests that the negative reports about the other manufacturer were not related to BIA-ALCL (which is discussed in the clause that precedes "as well as"), and as a simple matter of English grammar no reasonable investor reading the statement would have understood that the

second example referred back to the first, or that the two separately listed examples were really talking about the same phenomenon.

In any event, it reads far too much into statement (2) to suggest that it refers to relative incidence rates of BIA-ALCL among different manufacturers of textured breast implants. Neither the terms nor the concepts of "relative incidence rates," "BIA-ALCL," or "textured implants" are mentioned, or even alluded to, in the phrase "negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company."

In short, Plaintiff's explanation for why this clause is misleading is a "Hail Mary pass" of an argument – one that this court refuses to catch. In fact, it is arguably bad faith for Plaintiff to argue that a reasonable investor "could" read the clause as referring to the subject of the preceding clause when Plaintiff knows full well that it concerns another subject entirely, one that has nothing whatever to do with the subject matter of this lawsuit.

For these reasons, none of the four alleged misstatements can be deemed either literally false or misleading. Indeed, viewed on their own terms, every one of them was literally true.

2. The Alleged Misstatements Were Not False or Misleading In Context

Since the four alleged misstatements were literally true and not misleading, Plaintiff can only succeed on its falsity claim if it can show that some or all of Allergan's four statements were misleading because their generalized language regarding breast implants and BIA-ALCL failed to provide full context regarding the specific and greater association of BIA-ALCL and Allergan's textured implants. It fails in that endeavor.

The Second Circuit has held that, "Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 & n.3 (2d Cir. 2014). Whether a statement is misleading must be evaluated "not only by literal truth, but by context and manner

of presentation." *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (quoting *Operating Local 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 92 (2d Cir. 2010)) (internal quotations omitted).

At the motion to dismiss stage, reading the CAC in the light most favorable to the Plaintiff as was required, this court said that "assuming the allegations in the CAC are true," one could reasonably infer that "Allergan's implants were more closely associated with the incidence of BIA-ALCL than other breast implants on the market." *Allergan I*, 2019 WL 4686445, at *24. Therefore, the court went on to state, Allergan could be held liable if "a trier of fact were to conclude that Defendants' generalized statements about a possible association between breast implants and ALCL gave investors false comfort that Allergan's breast implants were no more closely linked to the cancer (or were less linked) than other products on the market." *Allergan I*, 2019 WL 4686445, at *24.

However, following extensive discovery, Plaintiff has failed to produce the requisite evidence to support their assertion set forth in the CAC. As it turns out, neither the scientific studies nor the regulatory community has determined that Allergan's textured implants are *in fact* more closely associated with BIA-ALCL than competitors' textured breast implants. Therefore, the disclosure that Plaintiff asserts should have been made would not have been "the whole truth."

a. The Scientific Studies Did Not Reach Definitive Conclusions Regarding Relative Incidence Rates of BIA-ALCL

The scientific studies that Plaintiff uses as support for its allegation that Allergan had the highest incidence rate of BIA-ALCL do not reach that conclusion.

First, Plaintiff cites to scientific studies (for example Gidengil and Brody) that do not even try to calculate incidence rates, but only provide the number of reported cases of BIA-

ALCL by manufacturer (when the identity of the manufacturer was available). (*See e.g.*, Dkt. No. 399 at 11, 14-15; Dkt. No. 368 at 5-7). Because these studies do not evaluate information that one would need to have in order to calculate relative incidence rates and comparative riskiness across manufacturers – particularly data relating to various manufacturers' market share or time on the market – they do not establish that use of Allergan's textured implants is in fact more closely associated with BIA-ALCL than use of the implants manufactured by others.

For example, the Gidengil study reported 54 cases of BIA-ALCL, 19 of which were associated with Allergan implants, 3 with Nagor implants, and 1 with Silimed implants. (Pl.'s 56.1 Counter ¶¶ 415-417). However, the researchers acknowledged that "not all manufacturers labeled their implants in the past" – and, indeed, manufacturer information was missing for 31 of the 54 cases under examination, or 57.4% of the data. (Defs' 56.1 ¶ 75). Moreover, the reader has no idea whether Allergan's 19 reported incidents represented 10%, 1%, 0.1%, or 0.0001% of the total number of Allergan textured implants placed in patients – or whether Silimed's 1 implant represents 0.1%, 1% or 10% of the total number of Silimed implants used in women needing reconstructive surgery. Without that sort of data, it is impossible to assess which implants are, relatively speaking, "safer."

Similarly, the Brody study identified 173 cases of BIA-ALCL, of which 97 cases were associated with Allergan implants. However, manufacturer information was missing for just over one third of the cases examined – 61 of the 173 cases. (Defs' 56.1 ¶ 86). And the very same information needed to draw conclusions about relative incidence rates is conspicuously missing from the Brody study, as it was from the Gidengil study. Significantly, the study's authors drew no conclusions about relative incidence rates. (Pl.'s 56.1 Counter ¶ 78).

Plaintiff points to the fact that internal Allergan data showed that Allergan knew about more cases of BIA-ALCL involving its textured implants than cases involving its competitors' products. But again, raw numbers of cases do not demonstrate relative safety levels – especially when there were so few cases to begin with. In its December 31, 2016 internal report, Allergan had identified 376 confirmed and suspected cases of BIA-ALCL, 249 of which were in women who had used its products. But the only cases for which Allergan could be sure to have data were Allergan's own products. Joseph Purpura, Head of Device Safety at Allergan, testified that often Allergan did not have access to reliable data for BIA-ALCL cases reported by its competitors, and so its data reflected only cases that were incidentally identified or accidentally reported to Allergan by customers. (DSJ Ex. 70 at 108, 261). And in 80 of the cases known to Allergan (again, almost one third of the cases it knew about) no manufacturer was identified.

Plaintiff only points to two research studies that attempted to calculate incidence rates, rather than simply compiling case numbers – the Doren Study and the Loch-Wilkinson study. Plaintiff alleges that these two studies show Allergan's Biocell implants had by far the highest rate of BIA-ALCL. (Dkt. No. 399 at 11).

However, the researchers who conducted these two studies pointed out that there were significant limitations in their data, which necessarily affected the accuracy of their calculations and the conclusions they were able to draw.

The Doren Study reported incidence rates for only two implant manufacturers – Allergan and Mentor – although there were more than two manufacturers of textured breast implants during the period covered by the study. (DSJ Ex. 36 at 1042-1046; Def's 56.1 ¶ 91).[5] Moreover,

[5] Other breast implant manufacturers before and during the class period included Mentor, Motiva, Sientra, Silimed, Laboratoires Arion, Cereplas, Nagor, Eurosilicone, Groupe Sebbin, Guangzhou Wanhe Plastic Materials, Hans Biomed, Polytech Health and Aesthetics, Ideal Implant, and Poly Implant Prothèse. (Defs' 56.1 ¶ 10).

it cautioned that "limited and incomplete data with significant confounders such as reporting bias, brand identifier labeling differences over time, and surgical technique variation may significantly skew conclusions about the frequency of events associated with a particular device." (DSJ Ex. 36 at 1048-1049, Def's 56.1 ¶ 94). Furthermore, the Doren study researchers were able to identify the manufacturers for just over half of the implants in the cases studied. They explicitly stated, "Without knowing the manufacturer for 49 percent of the study population, it was impossible to determine the true incidence of the disease by implant manufacturer." (DSJ Ex. 36 at 1048, Def's 56.1 ¶ 95). Therefore, it is impossible to conclude that Allergan's failure to disclose the results of the Doren Study – which were publicly available in any event – resulted in the suppression of true facts of which the market ought to be aware.

The Loch-Wilkinson Study reported incidence rates for only three implant manufacturers – Allergan, Mentor, and Silimed. (DSJ Ex. 74 at 650; Def's 56.1 ¶ 112). The authors also noted that, "The risk for [Silimed's Polyurethane] is confounded by a shorter duration of exposure in the Australian and New Zealand market compared with the other two textures [Allergan's Biocell and Mentor's Siltex] and will need further monitoring and updates." (DSJ Ex. 74; Defs' 56.1 ¶ 119). According to the study, most cases of BIA-ALCL present between 7 and 9 years following insertion of the implant. (DSJ Ex. 74 at 839). So a product that has been on the market for a longer period of time (i.e., Allergan and Mentor's textured implants) would have more reported cases than another equally risky product (i.e., Silimed's Polyurethane) that had been on the market for a shorter period of time. And in fact, when the study was updated a few years later, the researchers would conclude – based on the type of data that was missing in 2017 – that implants from Silimed, not Allergan, presented the greatest risk of developing BIA-ALCL (*see infra*, pp. 29-30).

b. Global Regulators Declined to Draw Conclusions Regarding Incidence Rates

In addition to the lack of certainty in the few scientific studies looking at the relationship between BIA-ALCL and breast implants, regulators repeatedly stated publicly that no reliable conclusions could be drawn regarding relative incidence rates of BIA-ALCL by manufacturer.

Plaintiff asserts that "there can be no dispute that ANSM . . . had data establishing that there was a large overrepresentation of ALCL with Allergan's textured implants." (Dkt. No. 399 at 10). But while the ANSM indeed noted that Allergan's textured implants were "over-represented" in the number of cases of BIA-ALCL in France, (*see* Dkt. No. 399 at 4-5), the regulator explicitly declined to draw any conclusions regarding the incidence rate of BIA-ALCL with any particular manufacturer of textured implants. On July 6, 2016, the ANSM issued a public release, which noted that, "In the 29 cases diagnosed to date in France, Allergan brand textured breast implants are currently over-represented," but went on to state that its "review confirms the risk of the occurrence of BIA-ALCL associated with *one or more implants of various brands*" and indicated the ANSM would "continue its investigations" of BIA-ALCL "for all brands of breast implants." (Defs' 56.2 ¶¶ 195-96) (emphasis added).

Eighteen months later, in February 2018 (during the Class Period), the ANSM stated that "the experts vote for the fact that texture is an increased risk factor but specifying that *the data presented do not allow [them] to assess the type of texture that may be more involved in the occurrence of an ALCL.*" (DSJ Ex. 122 at 12; Defs' 56.1 ¶ 197) (emphasis added). The report further noted that, Allergan "had the majority of the French market for textured implants for several consecutive years" and that "a statistical study has not been carried out to compare BIA-ALCL cases with implant brands while taking sales into account." (DSJ Ex. 122 at 12; Defs' 56.1 ¶ 197).

Moreover, beyond the ANSM, other countries' regulators stated repeatedly during the class period that there was insufficient evidence to show that any manufacturer was more linked with BIA-ALCL:

- In July 2017, the UK Medicines and Healthcare products Regulatory Agency stated that "[i]n the UK, there is currently ***no definitive evidence of an association with ALCL and any specific make or model of breast implant.***" (DSJ Ex. 90; Defs' 56.1 ¶ 64) (emphasis added).

- In November 2018, the Belgian health regulator, Superior Health Council, stated that "***observed associations of BIA-ALCL with certain implant types should be approached with caution.***" (DSJ Ex. 39 at 2; Defs' 56.1 ¶ 66) (emphasis added).

- In November 2018, the Dutch health regulator declined to recommend that women opt for smooth (not textured) implants, stating "***it is not yet clear whether women are not equally at risk or even more at risk of developing BIA-ALCL with this type of breast implant.*** We believe it is still too early to draw this conclusion from the research available thus far." (DSJ Ex. 127; Defs' 56.1 ¶ 204) (emphasis added).

- In February 2019, the FDA said that "not every report provides thorough information about each case, including what type of breast implant . . . the patient received, which ***makes it more difficult to know if any particular breast implant characteristic is associated with BIA-ALCL*** or if higher reports of BIA-ALCL are simply due to higher implantation rate of a particular manufacturer." (DSJ Ex. 92; Defs' 56.1 ¶ 67) (emphasis added).

- In April 2019, the Australian health regulator said that its breast implant expert working group "***identified gaps in the data currently available to inform an assessment of the true rate of BIA-ALCL*** in Australia particularly with different grades of texture." (DSJ Ex. 144; Defs' 56.1 ¶ 237) (emphasis added).

- In April 2019, the Swiss health regulator said that there was a "***lack of scientific evidence showing a causal connection between the use of a particular breast implant and the development of BIA-ALCL.***" (DSJ Ex. 145; Defs' 56.1 ¶ 239) (emphasis added).

Since both the scientific studies and the global regulators refused to draw any definitive conclusions regarding the incidence rates of BIA-ALCL and particular breast implant manufacturers, Allergan would have been lying, not telling the truth, if it had stated publicly that its implants were more closely associated with BIA-ALCL than were implants manufactured by other companies.

Nor was Allergan obligated to state that there would be a recall of its textured implants based on any "closer association" posited by Plaintiff.

Plaintiff asserts that Allergan was aware, at the time it made its alleged misstatements, of the possibility that its products would be recalled, based on the links shown in these studies. (Dkt. No. 399 at 6). However, not only had a closer link not in fact been established, but also – contrary to Plaintiff's assertions – the evidence in fact suggests that the regulators did not put Allergan on notice regarding the possibility of a recall.[6]

The communications Allergan received from both the ANSM and the GMED in the lead up to the non-renewal of Allergan's CE marks and the ANSM Recall did not give any indication that Allergan's textured implants would not have their CE marks renewed or be recalled. As late as September 2018, the chairman of the ANSM's BIA-ALCL committee stated that Allergan's Biocell textured implants were "essential" and "often irreplaceable" and that "no-one is being accused of anything" and "Allergan is a responsible manufacturer" that "participate[s] in studies on this type of lymphoma in total transparency." (DSJ Ex. 123; Defs' 56.1 ¶ 199-200). Then, less than one month before the ANSM Recall, the French Minister of Health stated that "at this point, there is no health policy decision that would prohibit [textured implants]" and that "there are

[6] Some of the communications cited in this discussion are in the record as part of the report prepared by one of Allergan's proposed experts, Dr. Margaret Brackley. The court had some issues with Dr. Brackley's proposed testimony; in particular, I would not have allowed her to testify about "what Allergan knew" – precisely because the actual communications she cited in her report would be in the trial record and did not require interpretation by an "expert." A lay trier of fact reading these communications is perfectly capable of assessing what the regulators had communicated to Allergan. However, there was nothing inadmissible about the underlying communications themselves – especially when offered for the fact that they were said, which is why they would be relevant on the issue of whether Allergan should have expected a recall. A statement not offered for the truth, but for the fact that it was said, does not fall afoul of the hearsay rule. (Fed. R. Evid. 801(c)(2)). As they are part of the record that was submitted on the motions for summary judgment and Plaintiff does not contest that these statements were made, the court sees no reason to ignore them simply because they appear in an expert report rather than as independent attachments to the moving papers.

cases where it is better for women to have a textured implant, so if we ban them completely, we will put a number of women in difficulty." (DSJ Ex. 126; Defs' 56.1 ¶ 203).

Likewise, the GMED communications did not indicate the possibility that the CE marks for Allergan's textured implants would not be renewed, but instead suggested that renewal was in fact possible until right before the decision was released. Indeed, Allergan's regulatory affairs executive director Kelly Carty testified that "The recall that happened in Europe in 2018 was unexpected" and that "up until the very . . . last days, really even the night before" Allergan was not aware that it "wouldn't be able to resolve the matter with the [GMED] regarding the nonrenewal." (DSJ Ex. 70 at 298; Defs' 56.1 ¶ 219). Her testimony was unrefuted.

On August 3, 2018, Allergan submitted to the GMED its CE mark renewal files for several of its breast implants and tissue expanders – including the Biocell and Microcell implants. Earlier in the year, Allergan had submitted Clinical Evaluation Reports ("CERs") (which assess the safety and performance of medical products and are required to obtain CE marking) for its Biocell, Microcell, and certain smooth implants, as well as a request to update its Instructions for Use ("IFU") on its breast implant labeling to harmonize language regarding BIA-ALCL across jurisdictions. (Brackley Expert Report, Dkt. No. 354-5 ¶ 19, 72, 74).

In October 2018, the GMED began responding to these Allergan submissions, asking Allergan to provide additional information: on October 17, 2018, the GMED requested more information in connection with the IFU request, which Allergan promptly provided, (*id.* ¶ 74); on November 30, 2018 the GMED first sent Allergan preliminary reviews of the CE mark renewal files, requesting updates to the materials that were submitted, (*id.* ¶ 76); and on December 3, 2018 the GMED requested an update to the IFUs that were submitted. (*id.* ¶ 77). In none of these

communications did the GMED state that it did not intend to renew Allergan's textured implants' CE marks.

Only in a December 5, 2018 call did the GMED first caution that, unless there was an explicit positive benefit risk profile for Allergan's textured implants, there was a possibility that their CE marks might not be renewed. (*Id.* ¶ 78). Even then, Allergan responded immediately to the GMED with additional documents summarizing the risk-benefit of its textured implants. (*Id.*) An internal Allergan communication from December 6, 2018 noted that "Allergan believes it can provide adequate responses to [the GMED's] requests and renew the CE certificates before the expiration date." (*Id.* ¶¶ 78-79). On December 13, 2018, Allergan requested information regarding the IFU updates, but the GMED simply responded that it was focused on the CE mark renewals. (*Id.* ¶ 80). Then, on December 14, the GMED released its decision not to renew to CE marks for Allergan's textured implants. (*Id.* ¶ 81).

As such, it was not until days before issuing its decision not to renew the CE marks for Allergan's textured implants that the GMED suggested any possibility that a non-renewal would occur. Rather, by requesting more information – especially regarding the labelling of breast implants – the GMED indicated that its review process for the various submissions was ongoing, and that Allergan's products would continue to be on the market. Significantly, every one of the allegedly misleading misstatement was issued well before these last-minute communications from GMED. Without any definitive statement from the GMED at the time the four statements were released, Allergan was not obligated to predict – and then disclose – that it would lose its CE mark and that its products would be recalled. Even then, nothing in the record indicates that either the loss of the mark or the recall was predicated on the "fact" (which turns out not to be a

fact) that its textured implants were more closely associated with BIA-ALCL than were the textured implants manufactured by others.

Significantly, even following the ANSM Recall, other global regulators noted their disagreement with the decision and did not suggest that any similar recall would occur in their countries. The European Taskforce on BIA-ALCL – a group of health regulators in 13 European countries, as well as the European Commission – stated that "all members of the Taskforce *with the exception of France*" (emphasis added) believed "that there is insufficient scientific evidence to limit the use of textured breast implants as they provide positive clinical and psychological outcomes for patients." (Defs' 56.1 ¶¶ 231-33, 241). The FDA likewise stated that "At this time, the FDA does not believe that, on the basis of all available data and information, the device meets the banning standard set forth in the Federal Food, Drug and Cosmetic Act." (*Id.* ¶ 241).

A company is not obligated to take "a gloomy, fearful or defeatist view of the future." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994); *see also Novak*, 216 F.3d at 309. The Second Circuit has also held that "it would be as serious an infringement of SEC regulations to overstate the definiteness of [an issue] as to understate [it]". *Dalberth v. Xerox Corp.*, 766 F.3d 172, 187 (2d Cir. 2014). The undisputed evidence adduced in this case shows that the "disclosures" Allergan allegedly did not make would have overstated the definiteness of scientific and regulatory belief about the relative safety of its implants vis a vis those of other manufacturers. That being so, Allergan was not required to adopt – nor should have adopted – a more pessimistic view than that of regulators and scientists by definitively stating that its textured implants were more closely associated with BIA-ALCL than textured implants of other manufacturers and that its implants would be recalled for that reason.

c. *Post Class Period Studies Conclude That Allergan Was Not More Closely Associated with BIA-ALCL*

Finally, recent studies on BIA-ALCL that have been published following the Class Period have concluded that Silimed polyurethane implants – not Allergan's textured implants – are most closely associated with the incidence of BIA-ALCL.

In May 2019, a study published in the Plastic and Reconstructive Surgery Journal updated the findings of the 2017 Loch-Wilkson Study – one of the primary studies Plaintiff relies on in support of its assertion that Allergan's Biocell implants had the highest incidence rate of BIA-ALCL. The 2017 study had acknowledged that its results were confounded by the shorter duration that Silimed's textured implants had been on the Australian and New Zealand market. The 2019 study – with the benefit of more data – concluded that, while the largest number of cases of BIA-ALCL was found in women who used Allergan's Biocell implants, "Silimed polyurethane (grade 4 surface) is now associated with the highest risk of developing BIA-ALCL." (DSJ Ex. 76; DSJ Ex. 47; Defs' 56.1 ¶¶ 130-138). These findings were first reported in the media during the Class Period, in May 2018. (Defs' 56.1 ¶ 138).

Then, in the 2020 edition of the Aesthetic Surgery Journal, another study updated the findings of the 2017 Loch-Wilkson Study findings for BIA-ALCL cases in Australia. This study found that "The highest risk [of BIA-ALCL] was calculated for Silimed Polyurethane implants." (*Id.* ¶¶ 139-140).

"To form the basis of liability an affirmative statement must be false and an omitted fact must be true." *In re Dynex Cap., Inc. Sec. Litig.*, 2009 WL 3380621, at *6 (S.D.N.Y. Oct. 19, 2009). These studies suggest that, should Allergan have disclosed that its textured implants were more closely associated with BIA-ALCL than any other textured breast implants, its statement would have been literally false.

Plaintiff argues that these two follow-up studies should not be considered because they were published after the Class Period and that evidence of falsity must be contemporaneous. (Dkt. No. 399 at 9). However, first, the results of the 2019 study were in fact published in the media during the Class Period – in May 2018. But Plaintiff's assertion also misstates the law. A statement lacks contemporaneous falsity if it is believed to be true when made, but later shown to be false. *Novak*, 216 F.3d at 309. However, "where a plaintiff asserts the falsity of a statement, the plaintiff must plead that it was both objectively false and disbelieved by the defendant at the time it was expressed." *In re China Mobile Games & Ent. Grp., Ltd Sec. Litig.*, No. 14-CV-4471 (KMW), 2016 WL 922711, at *3 (S.D.N.Y. Mar. 7, 2016) (internal citations omitted). Thus, if a statement is revealed to be true – even following the Class Period – Plaintiff cannot prove that it was "objectively false." Likewise, an omission can only exist if the corporate statement would otherwise be "inaccurate, incomplete, or misleading." *Stratte–McClure*, 776 F.3d at 101. A statement cannot be misleading if it did *not* include an inaccurate fact.

In summary, even drawing all reasonable inferences in Plaintiff's favor, as the Court must, Plaintiff has not produced any evidence to support its claim asserted in the CAC – that Allergan's implants are more closely associated with BIA-ALCL than competitors' textured breast implants. Without evidence of this association, there can be no genuine dispute as to whether Allergan made any misstatement or omission.

B. Plaintiff Fails to Raise A Genuine Dispute of Fact Regarding the Materiality of The Alleged Misrepresentations

Beyond failing to produce sufficient evidence of a misstatement or omission, Plaintiff has also failed to produce evidence showing that any alleged misrepresentations were material.

"An alleged misrepresentation is material if there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares of

stock." *Singh*, 918 F.3d at 63 (internal quotation marks and citation omitted); *accord TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). Materiality turns on whether the statement "significantly altered the 'total mix' of information made available." *Id.* (internal quotation marks and citation omitted); *accord Basic*, 485 U.S. at 231–32.

SEC Staff Accounting Bulletin ("SAB") No. 99 states that "The use of a percentage as a numerical threshold, such as 5%, may provide the basis for a preliminary assumption that . . . a deviation of less than the specified percentage with respect to a particular item on the registrant's financial statements is unlikely to be material," but that "it cannot appropriately be used as a substitute for a full analysis of all relevant considerations." 64 Fed.Reg. 45, 151 (1999).

The Second Circuit, citing SAB No. 99, has held that "a misstatement related to less than 5% of a financial statement carries the preliminary assumption of immateriality" but that "Courts must also consider qualitative factors, which can turn a quantitatively immaterial statement into a material misstatement." *IBEW Loc. Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 390 (2d Cir. 2015). Such qualitative factors include, whether the misstatement "concerns a segment or other portion of the . . . business that has been identified as playing a significant role in the registrant's operations or profitability; involves concealment of an unlawful transaction; and whether a known misstatement may result in a significant positive or negative market reaction." *Id.* (internal citations omitted); *see also Hutchison v. Deutsche Bank Sec. Inc.*, 647 F.3d 479, 485 (2d Cir. 2011).

During the Class Period, Allergan's textured breast implant sales constituted approximately 0.8% of Allergan's global net revenue, and sales of textured breast implants in CE mark countries (the countries where they were taken off the market) represented 0.4% of the company's net revenue. (Defs' 56.1 ¶¶ 5-7). Moreover, Allergan's breast implant business as a

whole (inclusive of both textured and smooth implants) was not among Allergan's ten largest products during the Class Period. (DSJ Exs. 2, 3 at F-72; Defs' 56.1 ¶ 8). Therefore, at the outset, the alleged misrepresentations concerning Allergan's textured implants, which made up less than 1% of total revenues of the company, are "presumptively immaterial." *IBEW Loc. Union No. 58*, 783 F.3d at 391; *see also Hutchison*, 647 F.3d at 489 n.5; *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 204 (2d Cir. 2009).

Analysis of qualitative factors does not overcome this presumption.

Plaintiff asserts that Allergan's breast implant operations were part of the company's "crown jewel" aesthetics business, (Dkt. No. 399 at 16), so Allergan's misstatements regarding textured implants were material, because they concerned a "particularly important segment" of Allergan's business – even if they were small relative to the firm's overall revenues. *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 720 (2d Cir. 2011). However, textured implants made up only 3% of Allergan's aesthetics business during the Class Period, thus falling below SAB No. 99's preliminary 5% threshold. (Dkt. No. 424 ¶¶ 726-27). Moreover, Plaintiff only cites to one analyst who stated that Allergan's "broader aesthetics business" was its "crown jewel" – and he made the statement, not because of its small textured implant product line (which the analyst described as "modest") but because of products that were far more significant revenue drivers, notably Botox. (Dkt. No. 424 ¶¶ 726-27).

Plaintiff next argues that materiality exists in this case because "Allergan's implants were associated with a devastating disease in much higher numbers than other breast implants" (Dkt. No. 368 at 12) and "investors attribute great importance to safety and reputational issues" (Dkt. No. 399 at 17).

Of course, any case of cancer is "devastating" for the person affected and her loved ones. But the Second Circuit has squarely held that a statement is not made material merely because it concerns safety issues – especially for a heavily regulated business in the medical industry.

For example, in *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 50 (2d Cir. 1995), the defendant – a medical, specialty chemical, and agricultural and animal health products business – failed to disclose negative results of FDA inspections of one of their manufacturing plants, which ultimately resulted in the suspension of product sales. The Second Circuit found that the results of the FDA inspections prior to the product suspension, which identified dozens of "deficiencies" was not material information that should have been disclosed. *Id.* at 52. The Circuit Court held that "It would be unduly burdensome and impractical to publicly disseminate the results of every inspection" for a "world-wide company engaged in heavily regulated businesses." *Id.* at 53. Moreover, the plant concerned produced only ten of the company's "over a thousand products in over thirty countries." *Id.* at 52.

Similarly, in *Masters v. GlaxoSmithKline*, 271 F. App'x 46 (2d Cir. 2008), the Second Circuit held that a drug manufacturer not timely disclosing the results of research on the safety of its drugs in children was not material when the results were "financially immaterial." The Circuit Court considered that less than 3% of the drug's revenues came from prescriptions to children and that any effect on the drug would not impact the company's earnings, as it sold several other drugs in addition to the one at issue. *Id.* at 50-51.

Here, the scientific studies and regulatory reports regarding BIA-ALCL that were released during and prior to the Class Period do not support the assertion that it is a "devastating disease." In fact, the undisputed evidence shows that BIA-ALCL is both rare relative to the total number of women who receive breast implants and is rarely fatal. In 2017, approximately 30

million patients had textured implants in place. (DSJ Ex. 41 at 889). As of February 6, 2019, the FDA had identified just 457 reported cases of BIA-ALCL – *an incidence rate of 0.00001523%* – with just 9 reported deaths. (DSJ Ex. 54). Plaintiff itself do not dispute that BIA-ALCL has been described by regulators and in medical studies as a "rare" disease with a "very low incidence" rate. (Pl.'s 56.1 Counter ¶ 12). For example, the Doren Study noted that "The FDA maintains that all breast implants, textured and smooth, have a reasonable assurance of safety and efficacy and that ALCL remains a very rare disease." (DSJ Ex. 33 at 697). Likewise, the Brody study, quoting the FDA, stated that "the absolute risk [of BIA-ALCL] remains very low due to the extreme rarity of breast ALCL" and further noted that the data show zero to 10 cases annually out of "well over 10 million women with breast implants" in the United States. (DSJ Ex. 35 at 169). The ANSM likewise stated that BIA-ALCL is "rare compared to the number of breast implants inserted each year." (DSJ Ex. 38).

This being so, a requirement that Defendants' disclose uncertain information from preliminary studies about BIA-ALCL – a rare and often treatable disease associated with a product that provides less than 1% of Allergan's revenue – would result in pharmaceutical investors being flooded with warnings about every adverse event reported for each of the company's over a hundred products, no matter how infrequent the adverse event, how small the product line, or how tentative the findings. Doing so could "bring an overabundance of information within its reach, and lead management simply to bury the shareholders in an avalanche of trivial information – a result that is hardly conducive to informed decisionmaking." *Basic*, 485 U.S. at 231.

Finally, Plaintiff asserts that Allergan's misrepresentations were material because Allergan's stock price immediately experienced a statistically significant decline following the

ANSM Recall. (Dkt. No. 399 at 19). Plaintiff notes that a "decline in stock price soon after the disclosure of a misrepresentation suggests the misrepresentation mattered to investors." *Sec. & Exch. Comm'n v. Am. Growth Funding II, LLC*, No. 16-CV-828 (KMW), 2018 WL 6322145, at *3 (S.D.N.Y. Dec. 4, 2018).

However, "Stock price movement is some evidence of materiality, but it is not in and of itself conclusive." *Veleron Holding, B.V. v. Morgan Stanley*, 117 F. Supp. 3d 404, 433 (S.D.N.Y. 2015). "Bare allegations of stock price declines cannot cure the immateriality of an overstatement as small as the one here at issue." *In re Duke Energy Corp. Sec. Litig.*, 282 F. Supp. 2d 158, 161 (S.D.N.Y. 2003), *aff'd*, 113 F. App'x 427 (2d Cir. 2004). Moreover, as described below in the discussion of loss causation, Plaintiff has failed to produce any evidence showing that the ANSM Recall "revealed" anything about relative BIA-ALCL incidence rates as among the various manufacturers of textured implants – the precise issue about which, according to Plaintiff, investors were misled. (*See infra* section III.C.). In fact, there is no evidence that relative incidence rates among various textured implant manufacturer had anything to do with the decision to cancel the CE mark, which led inexorably, under EU rules, to the recall. So while Plaintiff can tie the stock price decline to the loss of the CE Mark, it has failed to tie the stock price decline to a misrepresentation by Allergan that was "corrected" by the loss of the mark and the consequent product recall. As a result, the stock price decline proves nothing about materiality.

C. Plaintiff Fails to Raise A Genuine Issue of Fact on Loss Causation

A plaintiff suing for securities fraud must establish that the alleged fraud – in this case, the non-disclosure that Allergan's textured implants were more dangerous than the textured implants made by other manufacturers – was the cause of its investment loss. 15 U.S.C. § 78u-4(b)(4); *Dura Pharm., Inc. v. Broudo,*544 U.S. 336, 338 (2005). Merely purchasing securities at an inflated price

will not suffice. *Dura Pharm.*, 544 U.S. at 342. Rather, one must demonstrate "that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omissions concealed something from the market that, when disclosed, negatively affected the value of the security." *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 172 (2d Cir. 2005).

Plaintiff asserts that the stock price decline following the ANSM Recall was caused by the revelation of the truth that Allergan's textured implants were more closely associated with BIA-ALCL than other companies' textured implants. (Dkt. No. 399 at 27). But that is simply not so. I repeat: Plaintiff has not produced any evidence – not a scintilla – tending to show that the ANSM Recall revealed any new information about relative BIA-ALCL incidence rates across manufacturers of textured breast implants to the market. Plaintiff has not even shown that the relative incidence rates of BIA-ALCL across manufacturers of textured implants played any role in the decision to recall Allergan's products. Instead, the evidence shows that the ANSM Recall was solely a result of the GMED's decision not to renew the CE marks for Allergan's textured implants, which in turn was based on concerns unrelated to the relative risk of Allergan's textured implants as compared to other manufacturers' textured implants. It was related to GMED's concerns about the relative cancer risk of textured implants (by whomever manufactured) versus smooth implants, but there is no allegation in this case that Allergan made any misrepresentation on that subject.

The ANSM statement announcing Allergan's product recall specifically stated that the recall was prompted by GMED's declining to renew the CE marks for Allergan's textured implants when those marks were about to expire:

> Today ANSM was informed that the Allergan Medical Microcell and Biocell range of medical devices (breast implants and tissue expanders) are no longer CE marked as 17

> December 2018. The GMED, which has not renewed the CE marking of these devices as part of the procedure that takes place every 5 years, requested additional data from the manufacturer. These medical devices can no longer be sold in France and in Europe at present. Today ANSM asked Allergan to recall all products concerned which are currently stocked at health facilities.

(DSJ Ex. 132).

In turn, the GMED's letter advising Allergan of its decision made clear that, insofar as the non-renewal of the CE marks was based on concerns about textured breast implants, the concern was that textured implants might not be as safe as "alternative solutions such as smooth breast implants." (DSJ Exs. 136, 137).[7] At no point did GMED indicate that it was declining to renew the CE mark because Allergan's textured implants were more closely associated with BIA-ALCL than were textured implants manufactured by anyone else.

In the lead-up to the ANSM Recall, the ANSM also demonstrated that its concerns related to textured breast implants as a category, rather than specifically to Allergan's textured implants. In November, the regulator announced that a decision regarding the use of textured breast implants generally (i.e., by any manufacturer) would occur following expert committee meetings in February 2019. (DSJ Ex. 125; Defs' 56.1 ¶ 202). The ANSM Recall announcement itself also focused on the distinction between smooth and textured implants, stating that "it recommended health professionals to prefer the use of breast implants with a smooth envelope, pending the opinion of a committee of experts on the use of implants" and that it would "make a decision on the use of textured-envelope breast implants" after February 2019 expert committee meetings. (DSJ Ex. 132). In fact, the ANSM specifically noted that it had "not as yet identified any immediate health risk to women carrying the implants concerned." (DSJ Ex. 132).

[7] GMED also based its decision on "issues with the technical file assessed to demonstrate the conformity of the product to requirements of the [EU] directive" – which has nothing whatever to do with textured implants.

In April 2019, the ANSM did indeed recall all macro-textured and polyurethane implants. (DSJ Ex. 143). This means that Allergan's textured implants would have been recalled by ANSM whether or not they were more associated with BIA-ALCL as compared to other manufacturers' implants.

Plaintiff asserts that the fact that ANSM waited over four months after the Allergan recall to ban other textured implants means it believed that Allergan's textured implants were viewed by regulators as more dangerous than other manufacturer's implants. This, too, is not supported by the slightest bit of evidence. Allergan happened to be the only manufacturer of recalled implants whose CE mark was due to expire in France shortly before the ANSM's scheduled February 2019 Committee meeting – the one called to discuss whether any textured implants should remain on the market in Europe. (Defs' 56.1 ¶ 214). As noted in the ASNM Recall announcement, the earlier ANSM Recall of Allergan textured implants was prompted only by the fact that Allergan's CE marks had expired and not been renewed. Plaintiff does not and cannot point to a single piece of evidence indicating that ASNM recalled Allergan's implants in December 2018, rather than waiting until February 2019, because they were more dangerous or were more closely associated with cancer than were the implants that remained on the market for a few more months. If the recall and the resulting drop in Allergan's stock price led to Plaintiff's loss, that recall was not predicated on the alleged (and, as it turns out, literally untrue) "fact" that Allergan's textured implants were more dangerous than those of other manufacturers – which is the only theory being litigated here.

As Plaintiff does not draw the requisite causal connection between the information in the ANSM Recall and the fraud alleged, summary judgment on the issue of loss causation is appropriate. *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010).

II. Plaintiff Cannot Introduce New Theories Or Reintroduce Dismissed Claims

Perhaps aware that it has not produced sufficient evidence to show that Allergan's breast implants were more closely associated with BIA-ALCL than competitors' implants, Plaintiff throughout its briefing impermissibly seeks to reintroduce previously dismissed claims or assert new theories not set forth in the CAC.

First, Plaintiff alleges that Allergan implants were "strongly linked" with BIA-ALCL, rather than just "possibly linked," as Allergan disclosed. For example, in its summary judgment brief, Plaintiff asserts that there was a "clearly established connection between BIA-ALCL and Allergan's textured breast implants" and that there is "no dispute of fact that Allergan's textured implants were strongly and significantly associated with BIA-ALCL." (Dkt. No. 368 at 2, 5). Plaintiff repeats this assertion in its opposition brief to Defendants' motion for summary judgement, stating that, "Defendants were well aware of (or recklessly disregarded) material information clearly establishing that Allergan's textured implants were, not just possibly associated with BIA-ALCL but strongly associated with BIA-ALCL." (Dkt. No. 399 at 6). Likewise, Plaintiff's expert Marc Goodman states in his expert report that, "I believe that the focus [of Defendants' expert report] should be on the significant association of Biocell with the risk of ALCL, as shown by multiple well-established investigators, not whether other implant products may be equally risky." (Dkt. No 353-104 at 10).

By making these assertions, Plaintiff seeks to repackage a claim already made in the CAC and dismissed in this court's motion to dismiss decision. At the motion to dismiss stage, this court rejected Plaintiff's theory that Allergan made a false statement or an omission by not disclosing that there was a "definitive link", or otherwise a "plausible biological link," between its breast implants and BIA-ALCL. *Allergan I*, 2019 WL 4686445, at *13-14, *16-21, *25. I found – after reviewing the scientific and regulatory sources mentioned in the CAC – that no

such "definitive link" or "plausible biological link" had been pleaded. As a result, Allergan's disclosures of a "possible link" could not be deemed false or fraudulent. *Id.* at *19.

Plaintiff did not move to reconsider or move to file an amended complaint to revive this theory. As "summary judgment is not a procedural second chance to flesh out inadequate pleadings," Plaintiff cannot now at the summary judgment stage reassert its claim that Allergan made a misstatement by merely disclosing a "possible link" (rather than a "strong link") with BIA-ALCL. *Travelers Cas. & Sur. Co. v. Dormitory Auth.-State of New York*, 735 F. Supp. 2d 42, 82 (S.D.N.Y. 2010) (citing *Fleming v. Lind–Waldock & Co.*, 922 F.2d 20, 24 (1st Cir.1990)).

Plaintiff also seeks to introduce a new allegation about the extent of regulatory scrutiny that Allergan faced. Plaintiff alleges that "[Allergan] statements created the misleading impression that . . . Allergan had no notable concerns about increased regulatory scrutiny and the chance of being banned in Europe." (Dkt. No. 399 at 7) and that "Defendants failed to disclose that at least one European regulator . . . was concerned with the overrepresentation seen in Allergan implants in particular" (Dkt. No. 368 at 6). Plaintiff's expert Zachary Nye asserts in his expert report that "Plaintiff's theory is that [Defendant's disclosures] misrepresented . . . that Allergan's textured implants had been the subject of intense scrutiny from the ANSM throughout the Class Period." (Nye Class Cert. Reply, Dkt. No. 398-15 ¶ 20).

"A Plaintiff may not, in opposing a motion for summary judgment, rely on theories not set forth in the Complaint." *Johnson v. YWCA Residence, LLC*, 2014 WL 12782728, at *5 n.11 (S.D.N.Y. July 9, 2014); *see also Grandy v. Manhattan & Bronx Surface Transit Operating Auth.*, 2018 WL 4625768, at *5 n.5 (S.D.N.Y. Sept. 26, 2018). As this theory regarding the extent of regulatory scrutiny Allergan faced was not set forth in the CAC, it cannot be raised at the summary judgment stage.

If it were possible to consider this argument, I would reject it. The undisputed evidence fails to demonstrate that Allergan was subjected to greater regulatory scrutiny than was any other manufacturer of textured breast implants. Allergan was looked at in the fall of 2018 because its CE mark was due to expire in December – not because of any concern that its textured products were less safe than those of its competitors. If Allergan's CE mark had not been up for renewal when it was, there is no suggestion in the record that any regulator would have looked at it more closely than it was looking at all manufacturers of textured implants collectively.

III. Defendants' Motion For Summary Judgment on the Section 20(a) Claim is Granted

Section 20(a) holds liable any persons who "control" those found primarily liable under the Exchange Act. 15 U.S.C. § 78t(a)). Control person liability exists "to the same extent as" the controlled entity that committed the violation. *Id.*

As Plaintiff has failed to establish an underlying primary violation of Section 10(b) of the Exchange Act, Defendants' motion for summary judgment is granted on Plaintiff's Section 20 claims as well. *See In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 554 (S.D.N.Y. 2008), *aff'd*, 597 F.3d 501 (2d Cir. 2010); *Dresner v. Utility.com, Inc.*, 371 F.Supp.2d 476, 501 (S.D.N.Y.2005).

CONCLUSION

The only reason that is case was allowed to go forward on a limited basis following the motion to dismiss was because this court was required to draw all reasonable inferences from the CAC in Plaintiff's favor. Following discovery, Plaintiff has not in the end produced the required evidence to support its allegations made in its CAC.

Defendants' motion for summary judgment is GRANTED. Plaintiff's motion for summary judgment is DENIED.

The Clerk of Court is respectfully directed to remove Dkt. Nos. 326, 334, 345, 346, 347, and 351 from this court's list of open motions and to close the file.

Dated: December 12, 2022

U.S.D.J

BY ECF TO ALL COUNSEL