UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JENNIFER TUNG, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

BRISTOL-MYERS SQUIBB COMPANY, MICHAEL GIORDANO, FOUAD NAMOUNI, FRANCIS M. CUSS, GIOVANNI CAFORIO, LAMBERTO ANDREOTTI, and CHARLES A. BANCROFT,

Defendants,

1:18-cv-01611 (MKV)

OPINION AND ORDER GRANTING MOTION TO DISMISS

MARY KAY VYSKOCIL, United States District Judge:

This is a securities class action seeking damages for alleged misstatements made by Defendant Bristol-Myers Squibb Company ("BMS") and its executives concerning a clinical trial for a drug called Opdivo. In short, Plaintiffs accuse BMS of misleading the market about who was eligible for the trial by defining eligibility criteria without regard for a purported industry standard understanding of certain terms. It is alleged that as a result the market was led to believe the trial was substantially more likely to succeed than in reality. After the trial failed, BMS revealed to the market the full contours of the clinical trial, at which time some market analysts and investors expressed surprise at BMS's decisions regarding who was eligible for the trial. This lawsuit soon followed. Following appointment of Lead Plaintiffs in this case, and an initial round of briefing on a motion to dismiss, Lead Plaintiffs' Consolidated Amended Class Action Complaint ("CAC") was dismissed for failure to plead scienter. Lead Plaintiffs were granted leave to amend, and thereafter filed a Consolidated Second Amended Class Action

Complaint ("SAC").[1] Defendants again moved to dismiss. For the reasons that follow, and for substantially the same reasons warranting dismissal of Lead Plaintiffs' CAC, Defendants' motion is GRANTED.

BACKGROUND

The facts of this dispute are laid out in detail in the SAC, ECF #67, and in the opinion by Judge Oetken granting Defendants' motion to dismiss the previous complaint, ECF #66 ("CAC Opinion"). The facts as stated herein are drawn from the SAC and are assumed true for the purpose of this motion. *See Littlejohn v. City of New York*, 795 F.3d 297, 319 (2d Cir. 2015) ("At the motion to dismiss stage, we accept these allegations as true and draw all inferences in [Plaintiff's] favor.").

BMS is a pharmaceutical company. SAC ¶ 25. During the relevant class period—January 27, 2015 to October 9, 2016—the company was led by executives including Defendants Michael Giordano, Fouad Namouni, Francis M. Cuss, Giovanni Caforio, Lamberto Andreotti, and Charles A. Bancroft. SAC ¶¶ 26-33.

Plaintiff's allegations concern BMS's development of the drug Opdivo, and specifically the development of its use to treat non-small cell lung cancer ("NSCLC"). SAC ¶¶ 3-4, 7, 75. Opdivo is a "checkpoint inhibitor." SAC ¶¶ 39. Immune "checkpoints" are cellular mechanisms that prevent the body's immune system from attacking healthy cells. SAC ¶ 38. To treat NSCLC, Opdivo targets the checkpoint protein PD-L1, which is expressed by cells in the body to prevent the immune system from attacking them. SAC ¶ 38. Specifically, PD-L1 binds with the "PD-1" protein on T-cells to prevent the T-cell from attacking the PD-L1 expressing cell. SAC ¶¶ 38. However, cancer cells can also express the PD-L1 protein, thereby preventing the body's

[1] By order dated May 16, 2018, the Arkansas Public Employees Retirement System and the Louisiana Sheriffs' Pension and Relief Fund were appointed Lead Plaintiffs in this action.

immune system from attacking the cancer cells. SAC ¶ 39. By targeting cancer cells that are expressing the PD-L1 protein, Opdivo allows the body's immune system to attack the cancer cells. SAC ¶ 38. Using the body's own immune system to target and kill cancer cells in this way is the goal of the burgeoning field of "immuno-oncology." SAC ¶ 36.

The effectiveness of Opdivo and other checkpoint inhibitors depends on the level of PD-L1 expression in a patient's cancer cells (*i.e.* the share of cancer cells expressing the protein), commonly expressed as a percentage. SAC ¶¶ 49-51. Generally, the greater a patient's expression of PD-L1, the more likely treatment with a checkpoint inhibitor will be effective. SAC ¶ 3. It is estimated that approximately 70% of NSCLC patients exhibit some expression of PD-L1 on cancer cells, while approximately 25% of NSCLC patients exhibit a 50% or higher PD-L1 expression. SAC ¶ 3, 161. When developing trials to test the effectiveness of a PD-1 checkpoint inhibitor like Opdivo, companies like BMS have to determine a minimum expression level a patient must exhibit to be included in the study. SAC ¶¶ 77, 79. In making this decision, companies face a trade-off: the higher you set the cut-off, the more likely the trial will be successful, but the lower the cut-off, the more patients who are eligible for the trial and, ultimately, for any approved drug. SAC ¶¶ 10-11.

In January 2014, BMS announced a Phase III clinical trial for Opdivo called Checkmate-026 ("CM-026"). SAC ¶ 77. The goal of CM-026 was to determine whether Opdivo outperformed chemotherapy in treatment of NSCLC. SAC ¶ 77. If successful, CM-026 would have been the last step before BMS could seek approval to market Opdivo for use to treat NSCLC. SAC ¶¶ 75-77. BMS described that the purpose of CM-026 was "to show that [Opdivo] will improve [outcomes] in subjects with strongly Stage IV or Recurrent PD-L1+ non-small cell lung cancer when compared to chemotherapy." (emphasis omitted). SAC ¶ 79. While the trial was ongoing, in numerous statements, BMS also described the eligible class of

participants as exhibiting "strong" expressions of PD-L1. SAC ¶¶ 158-65. However, BMS also repeatedly stated throughout the class period that it would not provide any further information about its working definition of "strong." *See, e.g.*, SAC ¶¶ 93, 114.

Eventually, on August 5, 2016, BMS announced that CM-026 had failed to demonstrate that Opdivo was more effective than chemotherapy. SAC ¶ 11. The same day, BMS acknowledged for the first time that participants in CM-026 (*i.e.* those exhibiting "strong" expressions of PD-L1) only needed to exhibit expressions of 5% or higher. SAC ¶ 164. The price of BMS's common stock fell approximately 16% from August 4 to August 5, 2016. SAC ¶ 209. About two months later, on October 9, 2016, BMS announced that the data from CM-026 was unable to provide any statistically significant conclusions whatsoever about the effectiveness of Opdivo on NCSLC patients with expressions above 5%. SAC ¶ 13. On the next day of stock trading, the price of BMS's common stock fell approximately 10%. SAC ¶ 210.

This lawsuit was initiated in February 2018. *See* ECF #1. After Lead Plaintiffs were appointed, the Parties briefed Defendants' motion to dismiss the CAC. *See* ECF #51-53, 57, 62-63. The CAC was dismissed by Judge Oetken, to whom this case was previously assigned, based on Lead Plaintiffs' failure to plead scienter. *See* CAC Opinion at 5-11. Lead Plaintiffs were granted leave to amend and then filed the SAC. *See* ECF #67. The SAC seeks damages on behalf of a class of investors in BMS's common stock for BMS's alleged misrepresentations about the CM-026 trial targeting "strong" expressions of PD-L1. SAC ¶¶ 283-84. Lead Plaintiffs suggest that applying the label "strong" to participants with only a 5% expression contravened an industry standard understanding that an expression that low was understood to be among the lowest "merely positive" expressions, and was certainly not a "strong" expression. SAC ¶¶ 283-84. In support of this allegation, Plaintiffs point to previous studies, including a

roughly simultaneous clinical trial by BMS competitor Merck, which defined "strong" expression as 50% expression. *See* SAC ¶¶ 85, 96.

Defendants again moved to dismiss the SAC. Defendants argue that Lead Plaintiffs do not adequately allege scienter under the securities laws. *See* Memorandum in Support of Motion to Dismiss SAC, ECF #72 ("Def. Br."), at 8-20. This was the sole basis for Judge Oetken's previous dismissal of the CAC. The Defendants also argue here, however, that Lead Plaintiffs have not identified a false or misleading statement of fact, *see* Def Br. at 20-24, and that loss causation is not established. *See* Def. Br. at 24-25. Lead Plaintiffs opposed the current motion. *See* Memorandum in Opposition to Motion to Dismiss the SAC, ECF #74 ("Pl. Opp."). Defendants then filed a Reply. *See* Reply Memorandum in Support of Motion to Dismiss, ECF #76. The Court held oral argument on the motion on June 25, 2020. For the reasons that follow, the Motion to Dismiss is granted.

LEGAL STANDARD

"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 Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* When adjudicating a motion to dismiss, the Court "accept[s] all factual allegations in the complaint and draw[s] all reasonable inferences in the plaintiff's favor." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

Here, Lead Plaintiffs assert claims under Sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934 ("Exchange Act"). "Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI*

Commc'ns, Inc., 493 F.3d at 99. The heightened pleading requirements are set forth in Rule 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 ("PSLRA"). Under the PSLRA, a plaintiff must "specify each statement [or omission] alleged to have been misleading [and] the reason or reasons why the statement is misleading." *See* 15 U.S.C. § 78u-4. He or she must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind"—*i.e.* the intent "to deceive, manipulate, or defraud"—with respect to each act or omission. *Id.*

"In a typical Section 10(b) private action a plaintiff must prove (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." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). Relevant here, a plaintiff can prove scienter by showing either "(1) a 'motive and opportunity to commit the fraud'; or 2) 'strong circumstantial evidence of conscious misbehavior or recklessness.'" *Emps. Ret. Sys. v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015) (quoting *ATSI Commc'ns*, 493 F.3d at 99). "For an inference of scienter to be strong [as required], 'a reasonable person [must] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *ATSI Commc'ns, Inc.*, 493 F.3d at 99 (2d Cir. 2007) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007) (alteration in original)).

ANALYSIS

A. Lead Plaintiffs Fail To Plead Scienter

In his opinion dismissing the CAC, Judge Oetken ruled that Lead Plaintiffs failed adequately to allege scienter under either theory. *See* CAC Opinion at 6-11. First, he held that the motives alleged by Lead Plaintiffs for the alleged fraud were not sufficient to prove scienter.

Id. at 6-7. In short, the Court ruled, a desire to "protect competitively sensitive information" was ruled to be a non-actionable "generalized business motive." *Id.* Judge Oetken also ruled that any allegation that Defendants committed fraud "to sell stock while the price was artificially high" failed because Lead Plaintiffs had not alleged sufficient facts to lead to that inference. *Id.* at 7. Second, Judge Oetken also held that Lead Plaintiffs had not alleged "conscious misbehavior or recklessness" because "[e]ven if the Court assume[d] the existence of a fixed usage of 'strong' that excluded a PD-L1 expression cut-off of 5%, the complaint still fail[ed] to plead facts giving rise to a strong inference that the fixed usage 'was either known to the defendants or so obvious that the defendants must have been aware of it' at the time of the alleged misrepresentations." *See id.* at 8 (citing *ECA*, 553 F.3d at 198).

In the SAC, Lead Plaintiffs abandon any argument that scienter is proven by Defendants' motive to protect competitive information. Instead, Lead Plaintiffs focus their allegations on attempting to prove the existence of an industry-wide consensus on the meaning of "strong" in the context of PD-L1 expression. *See* Pl. Opp. at 9-15. They also argue briefly that motive can be inferred from the insider trading allegations in the SAC regarding stock trades by BMS executives. *See* Pl. Opp. at 15-17. Each of these arguments fails.

i. Conscious Misbehavior Or Reckless Conduct

Judge Oetken held, and, thus, it is law of the case that, Lead Plaintiffs cannot prove the existence of an industry standard simply by pointing to the definition of "strong" used by Merck, BMS's competitor who was running a simultaneous PD-L1 checkpoint inhibitor study. *See* CAC Opinion at 10; *see also Johnson v. Holder*, 564 F.3d 95, 99 (2d Cir. 2009) ("The law of the case doctrine commands that 'when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case' unless 'cogent and compelling reasons militate otherwise.'" (quoting *United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir.

2002))). Judge Oetken found that, at best, such allegations could prove that "Merck's definition of 'strong'" was greater than 5%, but that it did not determine any industrywide definition. *Id.* He stated that Lead Plaintiffs would need to cite a "publication, guidance, communication, document, or other specific source of information that could have alerted Defendants, at the time of the alleged misrepresentations, to an industrywide consensus that 'strong' PD-L1 expression was inconsistent with a 5% cut-off." *Id.* Only if an industry standard were established, could Plaintiff's cogently allege Defendants' conscious misbehavior or recklessness sufficient to establish scienter.

In response to that instruction, Lead Plaintiffs added three types of allegations to the SAC. First, Lead Plaintiffs have included statements and conclusions from a purported expert witness, Ronald H. Blum, a medical oncologist and researcher who has "participated in the independent oversight of late phase clinical trials, including clinical trials examining PD-L1 checkpoint inhibitors." SAC ¶ 9. Dr. Blum states that by the start of the class period in this case (January 27, 2015), there was an industry-wide consensus that 5% expression of PD-L1 was "low or minimal" and that 50% expression was "strong." SAC ¶ 9. Second, the SAC includes statements from a series of confidential witnesses who were former employees at BMS. The former employees explain that BMS executives were aware of Merck's usage of a 50% threshold as "strong" and that BMS was using a different number. SAC ¶¶ 71-72, 86-90. Finally, the SAC also includes certain other circumstantial evidence of wrongdoing that Lead Plaintiffs claim lead to an inference of scienter, such as BMS's stated intent to "harmonize PD-L1 assays" and the departure from BMS of certain individual Defendants. SAC ¶¶ 233, 279-80. Each of these new pieces of information is insufficient to remedy the deficiency in the scienter charge identified in Judge Oetken's opinion.

It is settled in this Circuit that plaintiffs may rely on testimony of confidential witnesses to bolster their complaint, provided that the witnesses are described "with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). Lead Plaintiffs' confidential sources are clearly described with sufficient detail in the SAC, which notes their roles at BMS and to which of the Defendants each spoke. *See* SAC ¶¶ 71-72, 87-90. However, Lead Plaintiffs' problem is not with the reliability of the sources but with what information they provide. The former employees claim only that BMS was aware of Merck's operating definitions and that BMS would have incorporated that information into "forecasting to understand the market." SAC ¶ 72. This information does not add anything new to the case. Lead Plaintiffs previously alleged in the CAC that BMS was aware of Merck's definition, and Judge Oetken held that knowledge was insufficient to prove anything other than Merck's definition of "strong." *See* CAC Opinion at 10.

The inference of scienter urged by Lead Plaintiffs is not "cogent" or "at least as compelling" as the opposing inference urged by Defendants. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Plaintiffs' unsupported allegations of BMS's knowledge and disregard of an industry standard are less convincing than Defendants' inference that even if BMS executives were aware of Merck's thresholds, they used a different definition in an attempt to reach a broader segment of cancer patients. Importantly, none of Lead Plaintiffs' sources can verify that BMS believed that Merck's thresholds represented an "industry standard" definition. Contrary to Lead Plaintiffs' contentions, *see* Pl. Opp. at 10-11, requiring proof from the confidential sources of BMS's direct knowledge of an alleged industry standard is not "smoking gun" evidence beyond what they are required to provide. *See Tellabs*, 551 U.S. at 324. Rather,

that missing information is necessary to support Lead Plaintiffs' suggested inference that Defendants were anything more than negligent in their design and execution of the CM-026 trial.

Plaintiff's reliance on Dr. Blum's testimony fares no better. A plaintiff can rely on expert testimony to bolster the factual allegations of its complaint, but the Court may not consider any legal conclusions offered by the expert. *See, e.g.*, *Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199, 224 (S.D.N.Y. 2018) (striking legal conclusions about Defendant's misrepresentations but considering expert's testimony about industry practices). Here, Dr. Blum's conclusions are proper except to the extent he opines that Defendants' statements were, in fact, misleading. *See* SAC ¶¶ 120-21, 137.

Dr. Blum concludes that an industry standard definition of "strong" and "low" PD-L1 expression existed by the beginning of the class period. *See* SAC ¶ 9. Leaving aside that his conclusion may be refuted by other evidence in the SAC, *see infra* at 12, and even accepting as true his assertion that such a standard existed in some or all of the immuno-oncology field, Plaintiff has provided evidence of that standard only through Dr. Blum. Failure to provide some other industry publication, guidance, or other evidence of such a standard, in addition to the expert testimony, is legally insufficient and requires that the Court not rely on Dr. Blum's testimony at all. *See Ong*, 394 F. Supp. 3d at 223 ("'[E]ven if non-opinion portions of an expert's affidavit constitute an instrument pursuant to Rule 10, opinions cannot substitute for facts under the [PSLRA].'" (quoting *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285-86 (5th Cir. 2006))); *accord In re CommVault Sys. Inc. Sec. Litig.*, No. 14-cv-5628 (PGS), 2016 WL 5745100, at *4-7 (D.N.J. 2016) (considering expert testimony only when plaintiff "d[id] not rely exclusively" on the expert) (cited at Pl. Opp. at 12).

The critical deficiency in Lead Plaintiffs' case is that even if the Court were to consider Dr. Blum's testimony, he states nothing that allows an inference that BMS executives had

knowledge of a new industry standard definition. Dr. Blum does nothing to bring his claim of an industry standard home to BMS. Instead, the SAC makes the conclusory allegation that Dr. Blum's understanding of an industry standard "should be imputed to Defendants." SAC ¶ 16. As Defendants' explain, Lead Plaintiffs have not alleged how or when an industry understanding reached BMS. *See* Def Br. at 13. This is particularly important since no one has suggested that that Dr. Blum has ever worked at BMS or is familiar with its procedures and practices. Without more, the Court cannot find that Dr. Blum's testimony establishes the existence of an industry standard or, more importantly, knowledge of such a standard at BMS. As a result, Defendants cannot be said to have knowingly or recklessly made statements which contradicted the putative standard.

The other information added to the SAC is circumstantial evidence that does nothing to further an inference of scienter. Lead Plaintiffs' note, for example, that BMS, in June 2015, committed that they "will participate in the efforts to harmonize PD-L1 expression assays." SAC ¶ 233. This statement actually supports the inference that no industry standard definitions existed in June 2015, as BMS was committing to "harmonize" approaches at that time, and not recognizing that they had already done so. As another example, Lead Plaintiffs bolstered their allegations regarding the "suspicious departures" of Defendants Cuss and Giordano from BMS. *See* SAC ¶¶ 279-80. Judge Oetken previously dismissed these allegations as not sufficient to plead scienter on their own. *See* CAC Opinion at 10 n.4. Because none of the new allegations add anything to the scienter analysis, the allegations remain insufficient. They hardly give rise to an inference of scienter that is "cogent and at least as compelling as any opposing inference" offered by Defendants, *Tellabs, Inc.*, 551 U.S. at 324, who persuasively argue that the departures were in the normal course of business and that BMS otherwise was not contradicting as as-yet-undeveloped industry-wide understanding of PD-L1 expressions.

Finally, the SAC incorporates by reference at least one document that seems to contradict Lead Plaintiff's arguments about the existence of an industry standard. *See Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) ("In certain circumstances, the court may permissibly consider documents other than the complaint in ruling on a motion under Rule 12(b)(6). Documents that are attached to the complaint or incorporated in it by reference are deemed part of the pleading and may be considered."). Specifically, in support of the argument that other industry participants adopted the 50% definition of "strong" expression of PD-L1, the SAC references industry presentations by BMS competitors and other groups using that terminology. *See* SAC ¶ 246.

In particular, the SAC mentions an October 8, 2015 presentation by Nektar, a pharmaceutical research company, at an industry conference in which the company "spoke about [Merck's PD-L1 inhibitor's] application for the 'subset of high PD-L1 expression of more than 50%.'" SAC ¶ 246. Defendants submitted with their motion papers a slide from that presentation, which occurred almost two years after CM-026 began and almost one year into the class period. *See* Reply Declaration of Matthew Solum in Support of Motion to Dismiss, ECF #76, Ex. 27 (the "Nektar Slide") at 3. That slide includes four different definitions of PD-L1 "positive" and two different definitions of "strong." *See* Nektar Slide at 3. Far from supporting the inference that an industry standard existed before the class period, the slide supports Defendants' argument that almost two years into the CM-026 trial, the industry had not yet settled on any standard, and thus that Defendants could not have knowingly misrepresented that its trial conformed to such a standard. Considering all of the allegations together, *Tellabs, Inc.*, 551 U.S. at 323, the Court again concludes that Lead Plaintiffs have not alleged a compelling inference of scienter based on Defendants' conscious misbehavior or reckless conduct.

ii. Fraudulent Motive And Opportunity

While Lead Plaintiffs largely devote their scienter arguments to proving "conscious misbehavior or recklessness," they have included some additional allegations of insider trading in the SAC, in an effort to prove Defendants had a fraudulent motive to mislead investors. While Judge Oetken previously rejected a version of this argument, *see* CAC Opinion at 6-8, the SAC adds new allegations about the trades. In particular, Lead Plaintiffs now allege that the Individual Defendants, most notably Andreotti, sold shares of BMS common stock before the failure of CM-026 was disclosed, resulting in a total profit of over $55 million. SAC ¶ 264. Even with the additions, however, these allegations do not rise to a level sufficient to lead to a strong inference of scienter.

Insider trading activity proves motive if the executive, who possesses information that the market does not, makes "unusual" trades in a way to avoid the ultimate loss due to the public disclosure of that information. *See In re Scholastic Corp. Secs. Litig.*, 252 F.3d 63, 74 (2d Cir. 2001). Unusual trades occur when an executive profits highly from sales, sells a large portion of his or her stock holdings, or trades drastically more stock during the class period than he or she did before. *Id.* at 7475. Here, Defendants convincingly argue, *see* Def. Br. at 9-10, that BMS executives sold the same overall percentage of the stock they owned before and during the class period. *See* Def. Br. at 9-10. Defendants further clarify that while executives experienced greater profits from stock sales, these were a result of Defendants receiving more shares as compensation overall during the class period and not opportunistic trading, since the same proportion was sold. *See id.* This uniform trading pattern, along with the fact that the vast majority of the trades in question were made pursuant to Rule 10b5-1 stock plans, defeats any inference that Defendants were motivated by profits. *See In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 585 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015) ("Trades made

pursuant to a Rule 10b5-l trading plan do not give rise to a strong inference of scienter."). Finally, Lead Plaintiffs have omitted information regarding the Defendants' total holdings. That omission is fatal to establishing scienter based upon trading activity. *See In re eSpeed, Inc. Secs. Litig.*, 457 F. Supp. 2d 266, 290 (S.D.N.Y. 2006).

Lead Plaintiffs are correct, however, that certain of the trades stand out. Namely, in May 2016, about two months after Defendants again claimed that CM-026 participants had a "strong" PD-L1 expression, Defendants Anderotti, Bancroft, and Caforio all sold significantly greater numbers of shares than previously had been their practice. *See* SAC ¶ 261. None of these trades were made pursuant to a Rule 10b5-1 plan. SAC ¶ 261. The trades came at a pivotal time during the CM-026 trial, after again describing the trial to the public, but shortly before the results were revealed. At argument, counsel for Defendants attempted to distinguish these trades on the basis that the results of CM-026 were not yet known. *See* Tr. of June 25, 2020 Oral Argument at 14:23-16:16.

While these trades are notable, in light of Lead Plaintiffs' pleading failures outlined previously, they cannot by themselves give rise to a strong inference of scienter. *See Tellabs, Inc.*, 551 U.S. at 324. This is especially true since the SAC alleges only three of the Individual Defendants made trades at that time, as Judge Oetken previously noted. *See* CAC Opinion at 7 (collecting cases); *see also San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 814 (2d Cir. 1996) ("[T]he fact that other defendants did not sell their shares during the relevant class period sufficiently undermines plaintiffs' claim regarding motive."). In short, Lead Plaintiffs have not provided sufficient facts to support a strong inference of scienter based on motive and opportunity to commit the fraud. As a result, Lead Plaintiffs' claims cannot stand.

B. Lead Plaintiffs Also Fail To Plead A Material Misstatement Or Omission

While Judge Oetken's CAC Opinion did not consider whether Lead Plaintiffs adequately pleaded false or misleading statements or omissions, the Court also concludes that the statements in the SAC are not material misrepresentations or omissions required for Section 10(b) liability. *See Stoneridge Inv. Partners, LLC*, 552 U.S. at 157 ("In a typical § 10(b) private action a plaintiff must prove (1) a material misrepresentation or omission by the defendant . . ."). As Lead Plaintiffs describe it, the SAC alleges three types of misstatements or omissions: (1) claims that CM-026 focused on "strong" PD-L1 expressions, when it did not, (2) failure to state exactly what the cutoff for CM-026 was, despite BMS noting from the outset that it would not do so, and (3) statements about BMS's confidence in the success of CM-026. *See generally* SAC ¶¶ 166-205. None of these types of statements are actionable.

First, BMS's decision to describe CM-026 as "strong" was not misleading. As described above, Lead Plaintiffs have not alleged facts sufficient to suggest that there was an industry standard definition of that term. Without such a definition, or indication that Defendants themselves agreed with Lead Plaintiffs' supposed definition before speaking, the statements are not actionable. *See, e.g.*, *In re Eros Int'l Secs. Litig.*, No. 15-cv-8956 (AJN), 2017 WL 6405846, at *5 (S.D.N.Y. Sept. 22, 2017) ("In the absence of a shared definition of the term . . . Plaintiffs must identify affirmative statements made by Defendant . . . that can plausibly be construed as false or misleading."). And, as Lead Plaintiffs themselves allege, throughout the class period, BMS declined to offer publicly any definition of the term "strong" as used in reference to the CM-026 clinical trial. SAC ¶¶ 93, 114. Moreover, the Nektar Slide discussed above indicates that in October 2015, industry sources both were aware that BMS's definition of "strong" was greater than five percent and that no industry standard definition of the term otherwise existed.

This defeats any argument that Defendants' use of "strong" to refer to PD-L1 expression in CM-026 participants was false in light of a supposed industry standard.

Second, Defendants' failure to disclose the actual cutoff for CM-026 also is not actionable. Lead Plaintiffs argue that this omission is actionable only because it would lead investors to believe that BMS was targeting a different category of patients than they actually were. Pl. Opp. at 20. However, this argument also depends on the existence of a purported industry standard understanding of "strong" when used in reference to the expression of PD-L1. Simply, if no industry-wide understanding exists, there is no reasons for investors to conclude anything in particular about CM-026. As discussed, Lead Plaintiffs have failed to allege such an industry standard. Lead Plaintiffs also assert that "Defendants' adoption of 'the exact same terms (e.g. 'strong' and 'high') used by Merck . . . was 'highly unusual and misleading' and 'disingenuous.'" Pl. Opp. at 20 (quoting SAC ¶¶ 80-81, 97). However, in the absence of an industry standard definition, no reasonable investor would have any particular understanding of those terms in light of Merck's usage, and Lead Plaintiffs certainly have not alleged particularized reasons why those descriptions would be materially misleading.

Lead Plaintiffs also assert that, even if Defendants had no duty to disclose the true cutoff for CM-026 at its onset, a duty to disclose developed during the trial. *See* Pl. Opp. at 23-24. In support of this assertion, Lead Plaintiffs note that "once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 583 (S.D.N.Y. 2016). Unlike the *Menaldi* case, however, Lead Plaintiffs have not alleged that Defendants gave any incomplete statements. Indeed, BMS fully described CM-026 using the terms as BMS understood them. No industry standard existed before the class period

here, and Lead Plaintiffs do not attempt to argue that an industry standard emerged during the class period.[2]

Finally, the other statements alleged in the SAC are non-actionable forward-looking statements or opinion. The Second Circuit has been clear that courts should not engage in *post hoc* analysis of a company's optimistic statements, but instead should look to whether plaintiff pleads facts sufficient to allege that the optimism was misleading. *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154–55 (2d Cir. 2013). Here, Lead Plaintiffs have failed to allege an industry standard understanding of "strong" that would have been inherent in any BMS executive's representations about the likelihood of success of CM-026. Instead, Lead Plaintiffs take issue only with statements that express an optimism about the future of BMS's business. Those are not actionable. *In re Sanofi-Aventis Sec. Litig.*, 2009 WL 3094957, at *4 (S.D.N.Y. Sept. 25, 2009) ("It is well settled that most forward-looking statements, such as predictions about future revenue, accompanied by cautionary language are not actionable under Rule 10b-5.").

In sum, largely for the same reasons that Lead Plaintiffs have not alleged scienter—because they have failed to establish an inference that there existed an industry standard understanding of a "strong" PD-L1 expression—the statements Lead Plaintiffs identify in the SAC are not actionable for Section 10(b) purposes.

C. Lead Plaintiffs' Claims Pursuant to Sections 20(a) and 20A Also Must Be Dismissed

The SAC includes two causes of action against the Individual Defendants, alleging control-person liability under Sections 20(a) and 20A of the Exchange Act. To establish a *prima facie* case of control-person liability however, a plaintiff must successfully allege a primary violation.

[2] The Court once again notes that the Nektar Slide, which was used at an industry conference in October 2015, almost two years into CM-026 and almost one year into the class period, stated that Merck and BMS had different definitions of "strong" and that the industry as a whole had no settled definition of PD-L1 positivity, with at least three different definitions reflected on that slide. *See* Nektar Slide at 3. Lead Plaintiffs assert that an industry standard was developed before the class period began, but the Nektar Slide alone demands a different conclusion.

See ATSI Commc'ns, Inc., 493 F.3d at 108. Because the Court concludes that Lead Plaintiffs' have not alleged scienter or a false statement, essential elements of a 10(b) claim, they have failed to allege any primary violation. As a result, the claims under Sections 20(a) and 20A also fail to state a claim and, accordingly, are dismissed.

CONCLUSION

Following dismissal of the First Amended Consolidated Class Action Complaint, Lead Plaintiffs' attempted to remedy the specific deficiencies identified in the Dismissal Order. Those efforts, as described herein, fall short. The Second Amended Complaint suffers from the same deficiencies as the first. Namely, Lead Plaintiffs have not alleged sufficient particularized facts to lead the Court to a strong inference of scienter as required by the PSLRA. The complaint fails to establish the existence of an industry standard definition relating to PD-L1 expression, as would be required to find that Defendants knowingly or recklessly disregarded the standard. Moreover, Lead Plaintiffs' allegations of insider trading, while in one small part notable, are collectively not sufficient to establish an inference of motive to commit fraud.

Additionally, Lead Plaintiffs' failure to allege the existence of an industry standard definition means that they also have failed to allege any materially misleading statement or omission.

As such, Defendants' Motion to Dismiss the Second Amended Consolidated Complaint is GRANTED and the complaint is DISMISSED WITH PREJUDICE. The Clerk of Court respectfully is requested to close the case.

SO ORDERED.

Date: September 30, 2020
New York, NY

MARY KAY VYSKOCIL
United States District Judge