20-3716-cv
Arkansas Public Employees Retirement System v. Bristol-Myers Squibb Co.

United States Court of Appeals
for the Second Circuit

AUGUST TERM 2021
No. 20-3716-cv

ARKANSAS PUBLIC EMPLOYEES RETIREMENT SYSTEM, LOUISIANA SHERIFFS' PENSION & RELIEF FUND, ERSTE-SPARINVEST KAPITALANLAGEGESELLSCHAFT MBH,
Plaintiffs-Appellants,

JENNIFER TUNG, Individually and on behalf of all others similarly situated, METZLER ASSET MANAGEMENT GMBH,
Plaintiffs

v.

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

ARGUED: OCTOBER 5, 2021
DECIDED: MARCH 11, 2022

Before: LIVINGSTON, Chief Judge, JACOBS, MENASHI, Circuit Judges.

Plaintiffs Arkansas Public Employees Retirement System, Louisiana Sheriffs' Pension & Relief Fund, and Erste-Sparinvest Kapitalanlagegesellschaft mbH appeal from the United States District Court for the Southern District of

New York's (Vyskocil, J.) grant of the motion to dismiss for failure to state a claim. The appellants fail to plead with particularity facts sufficient to show a material misstatement or omission or give rise to a strong inference of scienter.

We AFFIRM.

SALVATORE J. GRAZIANO, Bernstein Litowitz Berger & Grossmann LLP, New York, NY (Lauren A. Ormsbee, Jesse L. Jensen; Javier Bleichmar, Bleichmar Fonti & Auld LLP, New York, NY; William H. Narwold, Motley Rice LLC, Hartford, CT; Robert D. Klausner, Klausner, Kaufman, Jensen & Levinson, PA, Plantation, FL on the brief), for Plaintiffs-Appellants.

YOSEF J. RIEMER, Kirkland & Ellis LLP, New York, NY (Matthew Solum, Daniel R. Cellucci on the brief), for Defendants-Appellees.

DENNIS JACOBS, Circuit Judge:

This securities class action arises from a failed clinical trial conducted to ascertain whether a cancer drug in development would be more effective than chemotherapy in treating a specific type of lung cancer. Understanding the allegations of misstatement in the case requires a rudimentary understanding of the science.

Typically, the protein PD-L1 acts in healthy cells to bind with a second protein (PD-1) present on immune system T-cells to prevent them from attacking the healthy cells. This interaction is usually salutary, but when PD-L1 is present in cancer cells, the interaction can prevent the immune system from responding to the cancer cells as well.

The new drug, called a PD-1 checkpoint inhibitor, is designed to prevent the PD-L1/PD-1 interaction in cancer cells, so that they can be rendered vulnerable to the body's immune system. Not all cancer cells have the PD-L1 protein. The higher the percentage of cancer cells with PD-L1, the "stronger" the patient's PD-L1 "expression," and the more effective the drug in treating that patient. One parameter in the clinical trial of a PD-1 checkpoint inhibitor is the strength of expression in the population targeted by the trial, and that involves a trade-off. A trial limited to a population with higher expression has increased odds of success; a trial that also includes patients with lower expression expands the pool of patients to whom the drug can be prescribed if it succeeds, but such success may be less likely.

Defendant Bristol-Myers Squibb Co. acquired and developed a PD-1 checkpoint inhibitor now known as Opdivo, and disclosed that it was conducting a clinical trial. The disclosure did not specify the threshold of PD-L1 expression primarily targeted by the study. The disclosure stated generally that the study would target patients "strongly expressing" PD-L1.

About three years later, when Bristol-Myers publicly announced that the trial failed, it also disclosed for the first time that it primarily studied a patient population with PD-L1 expression of at least 5%. The claim in this suit is that 5% is not a "strong" expression, and that the class was thereby misled to overestimate the prospect of the trial's success. Over the ensuing months, the company and various commentators attributed the failure of the trial to the selection of a 5% PD-L1 expression threshold, as opposed to a higher level that would have narrowed the Opdivo trial to fewer patients but may have improved its chance of success.

Just a few months before the announcement of the results of the Opdivo trial, one of Bristol-Myers's principal competitors, Merck & Co., announced the success of a clinical trial on its comparable drug. Merck had described the

parameters of its clinical trial using similar language regarding "strong" PD-L1 expression, but eventually disclosed (prior to the study's conclusion) that in its trial, strong expression meant above 50%.

Following Bristol-Myers's announcement that the trial failed, its stock price fell. On February 21, 2018, several investors that owned Bristol-Myers shares in the relevant period filed this suit on behalf of a putative class in the United States District Court for the Southern District of New York (Vyskocil, J.). The Second Amended Complaint (the operative complaint, and hereinafter the "Complaint") alleges that the drop in stock price was attributable to the study's failure, and that Bristol-Myers had obscured the risk of such failure by declining to disclose the precise PD-L1 expression threshold and by misrepresenting that the study focused on patients "strongly" expressing PD-L1.

The district court dismissed the Complaint on a motion to dismiss for failure to state a claim. We affirm.

As the Complaint and documents on which it relies illustrate, rates of PD-L1 expression remained a topic of research throughout the putative class period; there was no generally understood meaning of "strong" expression that

contradicted Bristol-Myers's use of the term to mean 5%; and some observers correctly predicted Bristol-Myers's use of a 5% threshold before it was publicly disclosed. The Complaint also alleges no facts indicating that Bristol-Myers had an obligation to disclose the precise threshold--and Bristol-Myers cautioned the public that it would not do so.

Further, the Complaint fails to allege facts giving rise to a strong inference of scienter. The plaintiffs primarily argue that Bristol-Myers's knowledge of the industry understanding of PD-L1 expression rendered its misstatements intentional or reckless, but the Complaint fails to allege such an industry understanding.

The plaintiffs make two additional arguments. One is that scienter is evidenced by share sales by certain individual defendants, but those sales were made at a rate similar to prior periods, or pursuant to stock trading plans or for other procedural purposes, and the net effect of their transactions was to increase their total holdings. The other is that scienter is shown by Bristol-Myers's alleged reaction to the failure, including candid assessments of why it occurred

and the departure of two high-level employees; but these unremarkable responses to a disappointing result do not signify anything nefarious.

BACKGROUND

Arkansas Public Employees Retirement System, Louisiana Sheriffs' Pension & Relief Fund, and Erste-Sparinvest Kapitalanlagegesellschaft mbH (the "Investors"), along with other plaintiffs that did not appeal, bring this putative class action against Bristol-Myers Squibb Co. and individual officers of the company (collectively, "Bristol-Myers").[1] The Investors claim that Bristol-Myers violated the securities laws with material misrepresentations and omissions in describing a clinical trial it conducted on its drug Opdivo. The Investors claim

[1] The individual defendants are (1) Michael Giordano, Senior Vice President and Head of Development for Oncology and Immuno-oncology until July 25, 2016, when he resigned; (2) Fouad Namouni, Head of Oncology Development since July 25, 2016, and previously development lead for Opdivo; (3) Francis M. Cuss, Chief Scientific Officer and Executive Vice President; (4) Giovanni Caforio, Chief Operating Officer until May 5, 2015, and Chief Executive Officer from that date; (5) Lamberto Andreotti, Chief Executive Officer until May 5, 2015, and Executive Chairman of the board from that date through May 2, 2017; and (6) Charles A. Bancroft, Chief Financial Officer. All positions were held during the entire putative class period except where otherwise noted.

that Bristol-Myers's stock dropped precipitously when the trial failed to achieve its goal, allegedly due to factors concealed by the representations.

Because we assume the Investors' factual allegations to be true on review of a dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6), the following facts are taken from the Complaint and any documents upon which it relies. Lentell v. Merrill Lynch & Co., 396 F.3d 161, 165 (2d Cir. 2005).

A. Opdivo and the Clinical Trial

In 2009, Bristol-Myers acquired a pharmaceutical company developing a drug called "nivolumab," subsequently marketed as Opdivo. Opdivo is a type of immuno-oncology treatment referred to as a PD-1 checkpoint inhibitor, which treats various types of cancer by allowing the patient's immune system to fight the cancer directly. Some cancer cells have PD-L1 proteins that bind with PD-1 proteins present on immune-system T-cells, preventing the immune system from combatting the tumor. PD-1 checkpoint inhibitors block this interaction. Research on PD-1 checkpoint inhibitors shows that the level of PD-L1 present in a patient's cancer cells, referred to as "expression" and rendered as a percentage,

is positively correlated with the efficacy of PD-1 checkpoint inhibitors as a cancer treatment. The higher a patient's PD-L1 expression, the more effective a checkpoint inhibitor should be in treating the cancer.

After acquiring Opdivo, Bristol-Myers explored the drug's efficacy in treating several cancers, including non-small cell lung cancer ("NSCLC"), the most common form of lung cancer in the United States. The drug's use as a treatment for NSCLC was widely considered the most profitable potential use for PD-1 checkpoint inhibitors. A clinical study, announced on January 19, 2014, was commissioned to test Opdivo's efficacy as a first-line treatment of NSCLC. Bristol-Myers's announcement, published on ClinicalTrials.gov, stated that the Opdivo trial would focus on results among patients "strongly" expressing PD-L1.[2] Over the course of the study, Bristol-Myers regularly updated the ClinicalTrials.gov description without specifying the percentage of expression.

[2] The putative class period begins on January 27, 2015, when Bristol-Myers updated the trial data on ClinicalTrials.gov without adjusting the description of the primary patient population as those strongly expressing PD-L1, and ends on October 9, 2016, when Bristol-Myers shared full data from the trial for the first time.

On August 5, 2016, Bristol-Myers announced that the Opdivo trial failed to meet its primary goal--i.e., the drug did not show better results than chemotherapy in those "strongly" expressing PD-L1. The same announcement disclosed that the company defined "strong" expression in the Opdivo trial as 5% or greater PD-L1 expression. Over the following months, Bristol-Myers and investment analysts attributed the study's failure to the selection of 5% as the threshold for strong PD-L1 expression.

B. Industry Understanding of PD-L1 Expression

A few months after the Opdivo trial was announced, Bristol-Myers's competitor, Merck & Co. ("Merck"), announced a clinical study to test "Keytruda," Merck's PD-1 checkpoint inhibitor, as a treatment for NSCLC. In February 2016, Merck disclosed that, for the purpose of its trial, it defined "strong" expression as PD-L1 expression greater than 50%. On June 16, 2016, shortly before Bristol-Myers announced the failure of the Opdivo trial, Merck announced that Keytruda worked better than chemotherapy in patients with PD-L1 expression levels greater than 50%.

There was little consensus among industry participants and researchers as to the expression levels constituting "strong" PD-L1 expression and PD-L1 "positivity," which is the baseline level of expression at which a trial would consider a patient's PD-L1 expression as relevant to results. With respect to PD-L1 positivity, the July 2015 Journal of Thoracic Oncology surveyed the threshold used for "positive" expression in various studies, noting that many used 5%, while some used 1% or 10%. The publication showed that in several studies, Merck considered any expression up to 49% "weak." Similarly, a May 26, 2016 medical publication stated that "[t]he best cut-off percentage of scored cells to determine PD-L1 positivity . . . remains an unresolved question" but "the threshold most often chosen is >5% expression." JA-735 (Compl. ¶ 54). Several Opdivo studies conducted by Bristol-Myers prior to the relevant Opdivo trial defined positivity as greater than 5%, while others used 1%.

Sources also do not agree on the percentage that amounts to "strong" expression. On March 16, 2015, the journal PLOS One defined "strong expression" as at least 50%. On March 3, 2016, Translational Oncology defined "weak positive" as "1% to 49%" and "strong positive" as 50% or more.

Beginning with a press release on April 6, 2014, Merck consistently defined "strong" PD-L1 expression as at least 50%, and--as noted above--disclosed in February 2016 that it was using that same threshold in its trial.

Throughout the Opdivo trial, investment analysts tried to predict or discern its threshold for "strong" expression. Two months after Merck disclosed that its trial used a 50% threshold, an analyst asked if the trial used the same definition of strong expression. Bristol-Myers refused to disclose its definition of "strong" expression, but allowed that the "actual level of what strongly expressing PD-1 is [is] lower than 50%." JA-759 (Compl. ¶ 112). On March 7, 2016, SVB Leerink issued a report concluding that Bristol-Myers's "primary analysis population" "likely represents 30-40%" of lung cancer patients, a figure that indicated a patient population with PD-L1 expression of at least 25%. In June 2016, BMO Capital Markets stated with respect to the Opdivo trial that "we believe ['strong'] means at least 10%" expression. Goldman Sachs and Alliance Bernstein each predicted that the Opdivo trial used a 5% cut-off for "strong" expression. JA-1282, 1296, 1303, 1315.

C. The Allegations

The Complaint alleges that Bristol-Myers knew of an industry consensus that "strong" PD-L1 expression meant 50%, or could not mean 5%, and therefore misrepresented that the Opdivo trial's parameters targeted patients "strongly" expressing PD-L1, and made material omissions by failing to provide the exact threshold. Second, it is alleged that, in light of the choice to use a threshold of 5%, it was false and misleading for the company to express confidence in the study, to describe the study as "well-designed," or otherwise to state that the study would allow Bristol-Myers to bring Opdivo to market quickly.

It is alleged that these misrepresentations and omissions were made with the requisite scienter because (1) Bristol-Myers knew of the industry consensus regarding "strong" PD-L1 expression and acted recklessly or intentionally in disregarding it, given the likely impact of PD-L1 expression on the success of the trial and the importance of the trial to Bristol-Myers; (2) after announcement of the failure, Bristol-Myers implicitly conceded that the study was not designed to look at patients strongly expressing PD-L1; (3) Bristol-Myers defined 5% as a marker of minimal PD-L1 positivity in studies prior to and during the class

period; (4) certain officers left Bristol-Myers after the failure of the trial; and (5) certain individual defendants realized almost $55 million in profits by trading in Bristol-Myers stock during the class period.

The Complaint alludes to statements attributed to former Bristol-Myers employees, whose identities are kept confidential, and to an expert opinion from Dr. Ronald H. Blum, a medical oncologist. The former employees allegedly state that the individual defendants considered the Opdivo trial important and were personally involved in crafting it; felt PD-L1 expression was a crucial parameter for the trial; were aware of Merck's use of a 50% threshold in prior studies; and selected the 5% threshold after close consideration of its implications for the trial's success and Opdivo's potential profitability. Dr. Blum would allegedly testify, based on his experience in immuno-oncology and working on PD-1 checkpoint inhibitor research, that "there was an industrywide consensus among all major participants in the immuno-oncology industry" that 5% expression meant "low or minimal expression" and 50% expression was "strong" expression. JA-717 (Compl. ¶ 9).

In sum, the Complaint alleges that the misrepresentations and omissions were made with the requisite scienter and caused the price of Bristol-Myers stock to drop, that the Investors relied on the misrepresentations in purchasing or holding Bristol-Myers shares, and that they suffered losses as a result.

D. The Proceedings Below

On September 30, 2019, Judge Oetken dismissed the amended complaint without prejudice for failing to state a claim, holding that the Investors had not sufficiently alleged scienter. The Investors filed a second amended complaint and, on September 30, 2020, Judge Vyskocil (to whom the case had been transferred) dismissed it with prejudice for failure to state a claim, holding that the Investors failed to allege (i) material misrepresentations or omissions or (ii) facts giving rise to a strong inference of scienter.

DISCUSSION

We review de novo a district court's dismissal of a complaint for failure to state a claim. Stratte-McClure v. Morgan Stanley, 776 F.3d 94, 99–100 (2d Cir.

2015).

The Investors bring claims under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b) (the "Exchange Act"), and its implementing regulation, Rule 10b-5, 17 C.F.R. § 240.10b–5; Section 20(a) of the Exchange Act; and Section 20A of the Exchange Act, see Part IV. To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead: (1) a misstatement or omission of material fact; (2) scienter; (3) a connection with the purchase or sale of securities; (4) reliance; (5) economic loss; and (6) loss causation. Kleinman v. Elan Corp., plc, 706 F.3d 145, 152 (2d Cir. 2013). As the Investors failed to adequately allege a material misstatement or omission or facts giving rise to a strong inference of scienter, we affirm.

I

The district court properly took judicial notice of investment analyst reports from Goldman Sachs and Alliance Bernstein that correctly predicted the Opdivo trial's use of a 5% threshold for "strong" PD-L1 expression. "[I]t is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or

regulatory filings contained certain information, without regard to the truth of their contents[.]" Staehr v. Hartford Fin. Servs. Grp., Inc., 547 F.3d 406, 425 (2d Cir. 2008). When the court takes judicial notice of documents, it must rely on such documents only for the fact that the statement was made. Id. The Complaint refers to analyst reports that predicted a variety of possible PD-L1 expression thresholds higher than 5%, to argue that Bristol-Myers misled the market by describing a 5% threshold as capturing a population of strong expressors. The fact that other reports, relying on the same public information, correctly predicted Bristol-Myers's use of a 5% threshold is relevant to that argument and properly considered on this motion to dismiss. See Abdin v. CBS Broad. Inc., 971 F.3d 57, 60 n.2 (2d Cir. 2020) (taking judicial notice of scientific publications "for the publication of such information and relevant discussion in the scientific community").

The Investors also argue that the district court erroneously ruled that one document, a presentation slide submitted by Bristol-Myers in support of its reply brief, was incorporated by reference in the Complaint. (The document is

described in the margin.[3]) The challenge was waived. The Investors raised no objection to the district court's consideration of the slide, either at oral argument or in any subsequent filing. Such silence is sufficient to waive an argument on appeal. See Bayway Refin. Co. v. Oxygenated Mktg. & Trading A.G., 215 F.3d

[3] The Complaint quoted remarks at an October 8, 2015 presentation from Nektar, a pharmaceutical research company, which referenced Merck's focus on "PD-L1 expression of more than 50%" as evidence that "[t]he industry at large adopted Merck's presentation of 'strong' PD-L1 expression." JA-812 (Compl. ¶ 246). In its reply brief on the motion to dismiss, Bristol-Myers submitted a slide displayed during the same presentation which showed that, contrary to the Investors' characterization, Nektar discussed Merck's use of 50% among four different definitions of PD-L1 positivity and two different definitions of strong expression, indicating that no industry consensus existed. JA-1934. In holding the slide was incorporated by reference in the Complaint, the district court did not rule on whether the slide was integral to the Complaint, but the slide does contradict the Investors' selective quotation of the remarks. Although we do not reach the question here, we note that district courts may "permissibly consider documents other than the complaint" for the truth of their contents if they "are attached to the complaint or incorporated in it by reference[.]" Roth v. Jennings, 489 F.3d 499, 509 (2d Cir. 2007). A document that is integral to the complaint and partially quoted therein may be incorporated by reference in full. See San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc., 75 F.3d 801, 808–09 (2d Cir. 1996).

219, 227 (2d Cir. 2000).

II

The Investors failed to allege facts sufficient to show that Bristol-Myers made any material misstatement or omission in its descriptions of the Opdivo trial.

Section 10(b) "do[es] not create an affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). Just because "a reasonable investor would very much like to know [a] fact" does not create any obligation to speak up. Dalberth v. Xerox Corp., 766 F.3d 172, 183 (2d Cir. 2014). Disclosure is necessary only if there is a duty to disclose or "when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." Kleinman, 706 F.3d at 153 (quoting Matrixx, 563 U.S. at 44 (internal quotation marks omitted)).

Bristol-Myers had no obligation to disclose the precise percentage of PD-L1 expression which defined "strong" expression in the Opdivo trial. The Complaint confirms that such a disclosure likely would have been unwise.

Checkpoint inhibitors for NSCLC were expected to be highly profitable for pharmaceutical companies, and revealing the precise structure of the Opdivo trial would allow competitors to copy or undercut Bristol-Myers's target patient population (and reap the commercial benefit that Bristol-Myers hoped to realize from a successful trial). Bristol-Myers's competitors likely had even more desire than the Investors to learn the exact parameters of the Opdivo trial--but neither's interest created any duty to disclose.

Nor did Bristol-Myers make any false statement, or a statement that was incomplete, or one that was rendered misleading by the decision to withhold the exact PD-L1 expression threshold used in the trial. Under the Private Securities Litigation Reform Act ("PSLRA") and Federal Rule of Civil Procedure 9(b), allegations of material misstatements must be "state[d] with particularity" and must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 313, 321 (2007) (quoting 15 U.S.C. § 78u-4(b)(1)); Fed. R. Civ. P. 9(b). In other words, a complaint must, among other requirements, explain with particularity "*why* the statements were fraudulent." Gamm v.

Sanderson Farms, Inc., 944 F.3d 455, 462 (2d Cir. 2019) (emphasis added). "Allegations that are conclusory or unsupported by factual assertions are insufficient." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007).

The Investors fail to allege with particularity why any of Bristol-Myers's affirmative descriptions of the Opdivo trial were false or misleading. The Investors theorize that in the ClinicalTrials.gov description (and subsequent public statements) Bristol-Myers misrepresented that a primary goal of the Opdivo trial was to determine the efficacy of Opdivo on patients "strongly" or "highly" expressing PD-L1. The Investors argue that, in light of a general consensus that "strong" expression meant 50% expression or could not mean 5% expression, it was misleading to use the term while omitting the number. We disagree.

Bristol-Myers made clear at all times that it would not disclose the exact threshold or confirm speculation or predictions. And the Complaint directly contradicts the Investors' theory: there was no general understanding of what constituted strong expression, and therefore no reason for the Investors to

interpret "strong expression" to mean any specific threshold--nor any reason why the description was false or misleading. One journal quoted in the Complaint observed in May 2016 that "[t]he best cut-off percentage . . . to determine PD-L1 positivity . . . remains an unresolved question." JA-734 (Compl. ¶ 54). Moreover, the Complaint adduces a wide variety of definitions used for strong expression, ranging from 10% to 50%. The Investors argue that strong expression could not mean 5% because the industry and Investors understood 5% as the threshold for mere PD-L1 positivity or "weak" expression. But the Complaint details varied thresholds used for PD-L1 positivity, ranging from 1% to 49%, depending on the study. And the investment analysts at Alliance Bernstein and Goldman Sachs correctly predicted that Bristol-Myers defined strong expression as 5%.

"The veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers." Operating Loc. 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC, 595 F.3d 86, 92 (2d Cir. 2010). Since the Complaint itself reflects the lack of consensus on the meaning of strong or high expression, Bristol-Myers could not

mislead prospective buyers of its shares by using those terms.

Merck's description of its study as targeting strong expression, while using a 50% threshold, cannot reasonably be understood to bear upon Bristol-Myers's own internal definition of that term. The Merck clinical trial was announced *after* the Opdivo trial, and Merck's disclosure of its threshold occurred years later. When Merck finally disclosed its definition of strong expression, Bristol-Myers reiterated that it would not disclose the exact percentage, though it lifted the veil to disclose that the "actual level of what strongly expressing PD-1 is [is] *lower than 50%*." JA-759 (Compl. ¶ 112) (emphasis added).

Dr. Blum's expert opinion that there was an industry consensus as to the definition of strong PD-L1 expression does not change this analysis. Pursuant to Federal Rule of Evidence 702, an expert may testify "in the form of an opinion," and it is well established that "[t]o 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) (emphasis added) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Although it is permissible for a plaintiff to bolster a complaint by including a non-

conclusory opinion to which an expert may potentially testify, "opinions cannot substitute for facts under the PSLRA." Fin. Acquisition Partners LP v. Blackwell, 440 F.3d 278, 286 (5th Cir. 2006). Accordingly, Dr. Blum's opinion cannot rescue the Investors' claims, unless that opinion was based on particularized facts sufficient to state a claim for fraud. But the only facts on which Dr. Blum relied, according to the Complaint, are those already considered above and ruled insufficient. See JA-761 (Compl. ¶ 120) ("Dr. Blum reviewed Bristol-Myers' representations that [the Opdivo trial] focused on patients that exhibited a 'strong' or 'high positive' expression of the PD-L1 biomarker, and certain source documents referenced herein.").

The remaining statements that the Investors allege were false or misleading variably described the trial as "the quickest way to bring Opdivo to first-line patients," Compl. ¶ 166, a study designed with "great care," id. ¶ 193, or one in which Bristol-Myers had "great confidence," id. ¶ 173. None of these statements is actionable under the securities laws. Forward-looking statements, such as predictions regarding the trial's success and Opdivo's speed to market, are protected under the PSLRA if "accompanied by meaningful cautionary

statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement[.]" 15 U.S.C. § 78u-5(c)(1)(A)(i). All of the statements identified by the Investors were made on earnings calls or in presentations in which the relevant risk--that the trial may fail to reach its primary endpoint--was fully disclosed: for example, "[t]he public announcement of data from clinical studies . . . is likely to cause significant volatility in our stock price . . . . [T]he announcement of any negative or unexpected data . . . will likely cause our stock price to decline significantly." JA-1566. This "cautionary statement" identifies the particular risk that the Investors ran. And although they claim that Bristol-Myers had an obligation to disclose *why* the trial might fail--i.e., the selection of a 5% threshold--they cite no law to support such an argument.

Finally, Bristol-Myers's statements of subjective opinion, such as that the Opdivo trial was strongly designed, do not support a claim unless the statements of opinion "contained one or more embedded factual statements that can be proven false." Abramson v. Newlink Genetics Corp., 965 F.3d 165, 175 (2d Cir. 2020). The Investors make no allegations that the individual defendants'

opinions of the trial's design meet this standard. Although the Investors argue at length that the trial was riskier than the Investors (with hindsight) believe was necessary, they make no claim (and allege no facts indicating) that these statements of opinion were false. Accordingly, these statements are not actionable and are insufficient to state a claim.

III

The Investors also fail to allege with particularity facts giving rise to a strong inference of scienter. To do so, a complaint must allege facts showing "(1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 198 (2d Cir. 2009). If no motive or opportunity (other than a generalized business motive) is shown, the circumstantial evidence of conscious misbehavior "must be correspondingly greater" and show "highly unreasonable" behavior or that which evinces "an extreme departure from the standards of ordinary care[.]" Kalnit v. Eichler, 264 F.3d 131, 142 (2d Cir. 2001) (internal quotation marks and

citation omitted).

The Investors allege only one improper motive: the individual defendants' motive "to keep the price of stock high while selling their own shares at a profit." Appellant Br. at 55 (quoting In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 74 (2d Cir. 2001)). It is alleged that four of the six individual defendants engaged in stock sales during the putative class period; but the Investors fail to allege "unusual" stock trades as necessary to raise an inference of bad faith or scienter. See Scholastic Corp., 252 F.3d at 74–75. "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." Id. The trades detailed in the Complaint generated significant net profits, yet the sales of shares constituted a similar (or lesser) proportion of the individual defendants' trades as compared with the proportion of shares sold by those defendants before the putative class period. Further, the Investors failed to allege any facts illustrating the proportion of individual defendants' stockholdings involved in the sales compared to their overall holdings, but all four bought more shares than they sold during the

putative class period. Finally, the vast majority of the sales were conducted pursuant to a 10b5-1 trading plan or were executed for procedural purposes, and therefore could not be timed suspiciously.[4]

The Complaint likewise fails to allege "strong circumstantial evidence of conscious misbehavior or recklessness." ECA, 553 F.3d at 198. Bristol-Myers did not act recklessly or with intent in disregarding the industry's consensus definition of strong PD-L1 expression, because--taking the Investors' allegations as true--no such consensus definition existed. See supra Part II. Nor did the Investors allege facts indicating that Bristol-Myers knew of such an industry definition. Bristol-Myers's occasional prior use of a 5% threshold to show PD-L1 positivity shows only that Bristol-Myers used different parameters in prior

[4] The Investors allege that Andreotti, the individual defendant responsible for over 80% of the shares sold and the only one to use a 10b5-1 plan, entered into such plan during the putative class period, and therefore "the plan provides no defense to scienter allegations." Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford, 794 F.3d 297, 309 (2d Cir. 2015). But the Complaint fails to "sufficiently allege[] that the purpose of the plan was to take advantage of an inflated stock price," id., so the Investors have failed to allege facts indicating that the plan was not "given or entered into in good faith" or was "part of a plan or scheme to evade the prohibitions" of the regulations. 17 C.F.R. § 240.10b5–1(c)(1)(ii). Moreover, it is telling that Andreotti bought more shares than he sold during the putative class period.

studies. The Investors provide no reason why these studies obligated Bristol-Myers to use the same parameters in future drug trials. None of the former employees allege that Merck's use of a 50% threshold indicated an industry consensus; indeed, Bristol-Myers made clear to investors they were *not* using Merck's definition. And even assuming Dr. Blum's opinion alleged a contemporaneous general consensus, there is no indication anywhere in the Complaint that Bristol-Myers was aware of the opinion Dr. Blum expresses in this litigation or that Dr. Blum was personally aware of Bristol-Myers's knowledge of such a consensus.

Finally, Bristol-Myers's actions following the failure of the Opdivo trial similarly give rise to no strong inference of scienter. Bristol-Myers was candid in addressing why the trial failed, explaining that they had been confident in their study design and trial population, but that in hindsight the PD-L1 expression threshold was set too low. This conclusion was inescapable after the success of Merck's comparable trial but provides no information regarding Bristol-Myers's state of mind when initially describing the study. Similarly, Bristol-Myers changed the ClinicalTrials.org description to state that the threshold used was

5% expression; but accurately aligning that description with the newly public PD-L1 threshold was not an admission that the original, less-specific description was incorrect. And the departure of two high-level employees responsible for the trial, which occurred close in time to the announcement of the trial's failure, may reflect the importance that Bristol-Myers placed on the study's potential success, but is no reason to doubt the veracity or intent of Bristol-Myers's disclosures.

IV

To state a claim under Sections 20(a) and 20A of the Exchange Act, a plaintiff must allege a primary violation, such as one under Section 10(b) and Rule 10b-5. ATSI Commc'ns, 493 F.3d at 108. Because we affirm the district court's dismissal for failure to allege material misstatements or omissions or facts raising a strong inference of scienter, we address only those issues and affirm the dismissal of the claims under Sections 20(a) and 20A of the Exchange Act for

failure to allege a primary violation.

CONCLUSION

For the foregoing reasons, we **AFFIRM** the district court's grant of Bristol-Myers's motion to dismiss**.**