

United States Court of Appeals For the First Circuit

No. 15-1491

IN RE: ARIAD PHARMACEUTICALS, INC. SECURITIES LITIGATION

JOSEPH BRADLEY; PENSION TRUST FUND FOR OPERATING ENGINEERS; CITY
OF FORT LAUDERDALE POLICE & FIRE RETIREMENT SYSTEM; AUTOMOTIVE
INDUSTRIES PENSION TRUST FUND; WILLIAM A. GAUL, D.M.D.,

Plaintiffs, Appellants,

NABIL ELMACHTOUB, individually and on behalf of all others
similarly situated; JAMES L. BURCH, individually and on behalf
of all others similarly situated; GREATER PENNSYLVANIA
CARPENTERS' PENSION FUND, individually and on behalf of all
others similarly situated; JIMMY WANG, individually and on
behalf of all others similarly situated,

Plaintiffs,

v.

ARIAD PHARMACEUTICALS, INC; HARVEY J. BERGER; FRANK G. HALUSKA;
TIMOTHY P. CLACKSON; EDWARD M. FITZGERALD; JEFFERIES & COMPANY,
INC.; WAYNE WILSON; JAY R. LAMARCHE; BMO CAPITAL MARKETS CORP.;
ATHANASE LAVIDAS; COWEN AND COMPANY, LLC; RBC CAPITAL MARKETS,
LLC; JP MORGAN SECURITIES LLC; LEERINK SWANN LLC; NORBERT G.
RIEDEL; MASSIMO RADAELLI; ROBERT M. WHELAN, JR.; UBS SECURITIES
LLC,

Defendants, Appellees,

DAVID E. I. PYOTT; MIKE R. BOWLIN; JOHN T. CARDIS; WESLEY W.
VONSCHACK; ROBERT A. INGRAM; WILLIAM J. LINK; MICHAEL A.
MUSSALLEM; BARBARA J. MCNEIL,

Defendants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

Before

Howard, Chief Judge,
Souter, Associate Justice,*
Lipez, Circuit Judge.

John C. Browne, with whom Kristin Ann Meister, Bernstein Litowitz Berger & Grossmann, LLP, Ariana J. Tadler, Arvind Khurana, Melissa Ryan Clark, Milberg LLP, Johnathan Gardner, Carol Villegas, Labaton Sucharow LLP, Glen DeValerio, and Berman DeValerio were on brief, for appellants.

John F. Sylvia, with whom Andrew N. Nathanson, Matthew D. Levitt, Rebecca L. Zeidel, and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. were on brief, for appellees ARIAD Pharmaceuticals, Inc., Harvey J. Berger, Frank G. Haluska, Timothy P. Clackson, Edward M. Fitzgerald, Wayne Wilson, Jay R. Lamarche, Athanase Lavidas, Norbert G. Reidel, Massimo Radaelli, and Robert M. Whelan, Jr.

Brian E. Pastuszewski, with whom Mark Holland, Brian C. Devine, and Goodwin Procter LLP were on brief, for appellees Jefferies & Company, Inc., BMO Capital Markets Corp., Cowen and Company, LLC, RBC Capital Markets, LLC, JP Morgan Securities LLC, Leerink Swann LLC, and UBS Securities LLC.

November 28, 2016

* Hon. David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.

HOWARD, Chief Judge. When a company's stock declines, a shareholder lawsuit often follows. This case is no exception. Following a drop in the share price of ARIAD Pharmaceuticals, Inc., investors filed suit against the company and four corporate officers (together "ARIAD"), alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), as well as the Securities and Exchange Commission's ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5. The complaint also raised claims under Sections 11 and 15 of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. §§ 77k and 77o, against ARIAD, its directors, and various underwriters involved in the company's January 2013 offering of common stock. The district court stopped the litigation in its tracks by dismissing the complaint in its entirety. See In re ARIAD Pharm., Inc., 98 F. Supp. 3d 147 (D. Mass. 2015). The plaintiffs timely appealed.

We affirm the district court's dismissal of the securities fraud counts, except with respect to one particular alleged misstatement for which we find the allegations set forth in the complaint sufficient to state a claim. We also affirm the disposition of the plaintiffs' claims under Sections 11 and 15, albeit on different grounds than those articulated by the district court.

I. Facts

Fairly read, the complaint alleges the following. ARIAD Pharmaceuticals, Inc. is a publicly traded company headquartered in Cambridge, Massachusetts. At all times relevant to this litigation, Defendant-Appellee Harvey Berger served as ARIAD's Chairman and Chief Executive Officer ("CEO"), Defendant-Appellee Edward Fitzgerald served as the company's Executive Vice President and Chief Financial Officer ("CFO"), Defendant-Appellee Frank Haluska served as its Senior Vice President and Chief Medical Officer, and Defendant-Appellee Timothy Clackson served as its President of Research and Development, Senior Vice President, and Chief Scientific Officer.

In 2008, ARIAD embarked on the development of ponatinib,¹ a tyrosine kinase inhibitor ("TKI") designed to treat patients suffering from chronic myeloid leukemia ("CML"). As with any experimental drug, the development process entailed a series of clinical trials. See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 39 (1st Cir. 2008) (discussing typical three-phase trial structure). The first trial, dubbed "PACE 1," was intended to determine the maximum tolerable dose ("MTD") of ponatinib. After settling on 45mg as the MTD, ARIAD began a second trial, "PACE 2." The purpose of this follow-on

¹ ARIAD markets and sells ponatinib under the moniker "Iclusig."

study was to determine the safety, efficacy, and durability of ponatinib, in order to support its limited approval for CML patients who are resistant to or intolerant of other TKI treatments. In November 2012, with PACE 2 on-going, ARIAD began to screen subjects for its third clinical trial, "EPIC," which was designed to compare ponatinib directly against the leading CML drug on the market, Gleevec.

In July 2012, ARIAD began the process of submitting a rolling application to the FDA for limited approval to market ponatinib. In conjunction with the application, ARIAD submitted a July 2012 Interim Report consisting of data from the on-going PACE 2 trial, with a cut-off date of July 23, 2012. The Center for Drug Evaluation and Research ("CDER"), located within the FDA, subsequently analyzed the data and issued a series of reports of its own (collectively the "CDER Report").

By October 2012, ARIAD and the FDA began corresponding in earnest about potential approval of ponatinib for limited applications. As part of this process, ARIAD submitted a proposed label. The FDA, however, rejected ARIAD's proposal, citing concerns about adverse cardiovascular events and dosage reductions. On December 14, 2012, after some additional back-and-forth, ARIAD announced that the FDA had approved the marketing of ponatinib on a limited basis. It was not all good news, however, as the FDA required ARIAD to include a "black box" warning on

ponatinib's label about the risk of adverse cardiovascular events. Following disclosure of these developments, ARIAD's per share stock price fell from \$23.88 to \$18.93.

In the wake of the black box warning, ARIAD nevertheless continued to publicly project confidence in ponatinib. But more troubling news arose in October 2013. First, on October 9, ARIAD informed investors that, based on additional data from an August 2013 Interim Report, it was pausing enrollment in all clinical studies of ponatinib due to increased instances of medical complications in the PACE 2 trial. Days later, on October 18, ARIAD issued a Form 8-K and accompanying press release indicating that it had agreed to halt the EPIC trial entirely. Finally, on October 31, ARIAD announced that it was "temporarily suspending the marketing and commercial distribution" of ponatinib at the direction of the FDA. The market reacted harshly, and ARIAD's stock price fell to \$2.20 per share. The instant shareholder lawsuit followed.

II. Procedural History

On the defendants' motion, the district court dismissed the complaint in its entirety. As to the Exchange Act claims, the court found that the complaint sufficiently alleged material misrepresentations or omissions about ponatinib, but that it failed to give rise to a "strong inference" of scienter as required by the Private Securities Litigation Reform Act of 1995 ("PSLRA").

For the Securities Act claims, the district court held that the complaint did not plausibly allege any material misrepresentations or omissions in relation to ARIAD's January 2013 common stock offering.

We review the grant of a motion to dismiss for failure to state claim de novo.² See Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002). In doing so, we assume the truth of "the raw facts" set forth in the complaint. In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012). By contrast, we need not credit the plaintiffs' "legal conclusions or characterizations." Id.

III. Exchange Act Claims

Section 10(b) of the Exchange Act "forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device'" Tellabs Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (alteration in original) (quoting 15 U.S.C. § 78j(b)). The SEC has implemented this provision via Rule 10b-5, which proscribes, among other things, "any untrue statement of a material fact" or omission of any "material fact necessary in order to make the statements made . . . not misleading." 17 C.F.R. § 240.10b-5. To

² Because our review is de novo, we need not specifically address each of the plaintiffs' quibbles with the district court's analysis. See Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 241 & n.5 (1st Cir. 2015).

state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead the following elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)).

The only two elements implicated by this appeal are the existence of a material misrepresentation and scienter. Ultimately, because we find that the complaint fails to adequately plead scienter with respect to most of the alleged misstatements, we need not determine whether those statements contained any misrepresentations or, if so, whether such misrepresentations were material.

We have, however, recognized that "the materiality and scienter inquiries are linked." Abiomed, 778 F.3d at 240. This is because the marginal materiality of an omitted fact "tends to undercut the argument that defendants acted with the requisite intent . . . in not disclosing" it. Id. at 242 (citation omitted). Accordingly, we must bear in mind that a fact is material where there is "a substantial likelihood that" its disclosure "would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988) (citation omitted).

The Supreme Court has described scienter as "a mental state embracing intent to deceive, manipulate, or defraud." Tellabs, 551 U.S. at 319 (citation omitted). The plaintiffs correctly point out that scienter also encompasses "a high degree of recklessness." Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 649 F.3d 5, 20 (1st Cir. 2011) (citation omitted). But, in this context, recklessness requires "an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers . . . that is either known to the defendant or is so obvious the actor must have been aware of it." Id. (citation omitted).

At the pleading stage, the PSLRA requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with" scienter. 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). "To qualify as 'strong' . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, 551 U.S. at 314. We have found this exacting standard satisfied where the complaint "contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." Bos. Sci.,

686 F.3d at 31. In imposing this heightened pleading standard, Congress recognized and accepted the "[i]nherent" risk of leaving "without remedy some wrongs that discovery or trial might have disclosed." Id. at 32.

Here, ARIAD's alleged misstatements fall into two broad categories: (1) those made before the FDA's December 14, 2012 limited approval of ponatinib and the corresponding disclosures; and (2) those made after such approval. We address each of these categories in turn below, and, with the exception of one pre-approval statement, we agree with the district court that the complaint fails to give rise to the required strong inference of scienter. We also find the plaintiffs' allegations of insider trading insufficient to resuscitate the inadequate fraud claims.

A. Pre-Approval

The first alleged misstatement identified during the pre-approval period occurred in a December 11, 2011 press release about the PACE 2 trial data. The release indicated that "[i]nitial safety data show ponatinib to be well tolerated." It went on to list the rates of some adverse events, including rash, thrombocytopenia, dry skin, abdominal pain, headache, and pancreatitis, but it did not mention the rate of cardiovascular events. As required by the PSLRA, the complaint purports to explain "why the statement [wa]s misleading," 15 U.S.C. § 78u-4(b)(1), by referencing the CDER Report based on data collected

through July 23, 2012. The complaint identifies several similar statements by ARIAD about the safety of ponatinib between December 2011 and mid-July 2012. The plaintiffs claim that each of these statements was materially misleading in light of the data reflected in the CDER Report.

But the plaintiffs' theory of fraud suffers from a glaring omission. The complaint contains conclusory allegations that the defendants possessed "contemporaneous[]" knowledge of various facts in the CDER Report, including the 8% rate of serious cardiovascular events, "based on their continuous monitoring of the PACE 2 trial data." The plaintiffs do not, however, allege any specific facts about when the defendants learned of these adverse events or even when the adverse events occurred. Rather, they impermissibly seek to establish fraud by hindsight, suggesting that, as early as December 2011, the defendants must have known about adverse events occurring up until the July 23, 2012 cut-off date. Not only does this theory defy logic, it also ignores our caselaw's instruction that "[a] statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." Biogen, 537 F.3d at 45; see also id. at 50 (finding complaint insufficient to support inference of scienter where the plaintiffs "failed to allege when" the relevant adverse

events "became known"); Auto. Indus. Pension Tr. Fund v. Textron Inc., 682 F.3d 34, 39 (1st Cir. 2012) (affirming dismissal where "warnings by subordinates or expressions of concern by executives" were "notably absent").

The complaint's allegations about access to the PACE 2 data do not fill this gap. Only one such allegation relates to the pre-approval period, and it stands for the unremarkable proposition that, as of May 9, 2012, ARIAD was "in the process of collecting, QCing, [and] processing the data." The paragraph is silent on the crucial questions of when the serious adverse events occurred and when the defendants became aware of them.

In addition to statements about ponatinib's safety, the complaint also cites various allegedly misleading statements about dose reductions. For example, on December 12, 2011, Haluska, ARIAD's Chief Medical Officer, told investors, "we haven't quantified yet the number of dose interruptions or dose reductions" in the PACE 2 study. The plaintiffs' theory of fraud follows a familiar pattern: this statement was purportedly misleading because of the defendants' contemporaneous knowledge of certain facts in the CDER Report, including the fact that 73% of patients required a dose interruption or dose reduction. Subsequent paragraphs contain similar allegations. We are, however, left to guess as to precisely when the defendants became aware of the dose reductions.

For these reasons, we have little trouble concluding that the complaint fails to create a compelling inference of scienter with respect to statements made before the July 23, 2012 cut-off date for the CDER Report. Indeed, the plaintiffs come close to conceding as much by alleging that the defendants possessed knowledge of the relevant adverse events and dosage reductions "[b]y no later than July 23, 2012."

Arguably, the analysis could be different for time periods after that date if the defendants were familiar with the data that ARIAD provided to the FDA. But the complaint contains no such allegation. In fact, aside from a conclusory statement that Haluska "participated in the creation" of ARIAD's July submission, the complaint fails to indicate whether and to what extent the defendants were involved in collecting or reviewing the relevant data. Accordingly, we find the plaintiffs' allegations insufficient to state a claim with respect to the purported misstatements from July 23 through October 2012.

On October 25, 2012, the FDA sent an email to unspecified individuals at ARIAD rejecting the company's proposed label for ponatinib due to inadequate safety disclosures. The agency cited the 8% rate of serious cardiovascular events in the PACE 2 trial data, as well as the 73% dose reduction rate. A follow-up meeting was held on November 1, 2012, which included FDA personnel, Haluska, and Clackson, ARIAD's Chief Scientific Officer, among

others. After that meeting, the FDA directed ARIAD to submit a revised label with a black box warning.

In light of these later communications with the FDA, the plaintiffs' allegations are sufficient to support a strong inference of scienter with respect to one particular material misstatement.³ On December 11, 2012, an investment bank published a report on ARIAD based on a breakfast meeting the previous day with Chairman and CEO Berger, Haluska, and Clackson, among others. The report stated, in pertinent part, that "management continues to be optimistic about ponatinib's prospects for approval in the U.S. . . . with a favorable label." It further indicated that the drug's "profile continues to look very benign, with few worrisome

³ The plaintiffs point to two other purported misstatements between October 25 and December 11, 2012. The complaint fails to create an inference that these statements were knowingly false.

First, the plaintiffs cite Berger's November 7 response on an analyst conference call, "I can't speak to what the label [for ponatinib] is going to look like." Because ARIAD was, at the time, in negotiations with the FDA about the label, this statement was literally true. Nor was it materially misleading for Berger to omit certain details of the company's interactions with the FDA. See Abiomed, 778 F.3d at 244 (citing the need for "give and take" with the regulator).

Second, the plaintiffs take issue with ARIAD's November 9, 2012 Form 10-Q, which indicated that there had been "no material changes to the risk factors" included in the prior Form 10-K. Even assuming that this statement was materially misleading, the plaintiffs point to no allegation that Berger or CFO Fitzgerald, the two defendants who signed the document, were involved in the October 25 or November 1 communications with the FDA. Accordingly, the complaint fails to support a compelling inference of scienter.

signals." The report cited pancreatitis as "the most prevalent" serious adverse event (occurring in 5% of patients) and noted "low rates of cardiovascular issues."

Assuming these allegations are true, it was knowingly or recklessly misleading for Haluska and Clackson to express optimism about ponatinib's chances for approval with a "favorable label" weeks after learning that the FDA had rejected ARIAD's proposed label. While management may have held out hope of achieving this result, the expression of that hope without disclosure of recent troubling developments created an impermissible risk of misleading investors. See Zak v. Chelsea Therapeutics Int'l, Ltd., 780 F.3d 597, 610 (4th Cir. 2015) (finding "a strong inference that the defendants either knowingly or recklessly misled investors by failing to disclose critical information received from the FDA . . . , while releasing less damaging information that they knew was incomplete"). Similarly, after the FDA specifically noted the 8% rate of serious cardiovascular events, it was knowingly or recklessly misleading for ARIAD to cite pancreatitis as the most prevalent serious adverse event. See Aldridge, 284 F.3d at 83 ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter.").

ARIAD fails to develop any argument that these misstatements were not material, and, in any event, we have little

difficulty concluding that disclosure of the FDA's concerns or the rate of serious cardiovascular events with respect to ARIAD's leading product would have altered the total mix of information available to investors. For these reasons, we reverse the district court's dismissal of the Section 10(b) and Rule 10b-5 claims predicated upon this December 11, 2012 press release.⁴

B. Post-Approval

The plaintiffs' post-approval allegations rely on the same type of fraud by hindsight theory that doomed the majority of their pre-approval claims. It is undisputed that, on December 14, 2012, ARIAD disclosed to investors the 8% rate of serious cardiovascular events as well as the FDA's requirement of a black box warning. The complaint nonetheless identifies various subsequent statements about ponatinib that were purportedly misleading for failure to disclose an increase in the rate of adverse events after the July 2012 cut-off date. More specifically, the rate of serious cardiovascular events is said to have increased from 8% to 11.8%. The alleged misstatements occurred between March 1 and August 9, 2013, but the plaintiffs rely on data collected through an unspecified date in August to claim that those statements were fraudulent. Because the complaint

⁴ Because the district court dismissed the Section 10(b) and Rule 10b-5 claims, it also dismissed the derivative Section 20(a) claims without any additional analysis. We vacate that dismissal with respect to the December 11, 2012 release.

fails to indicate when the adverse events occurred, let alone when the defendants became aware of them, it fails to create a strong inference of scienter.

Nor do the plaintiffs' allegations of access to post-approval data get them over the PSLRA's pleading hurdle. To be sure, these allegations are more extensive and detailed than their pre-approval counterparts. But the plaintiffs still fail to allege specifically when the defendants became aware of any adverse events. See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1063 (9th Cir. 2014) (affirming dismissal despite alleged access to undisclosed data absent "allegations linking specific reports and their contents to the executives"). And, more fundamentally, the defendants self-evidently could not have been aware of adverse events that had not yet occurred. The complaint is silent with respect to the rate of adverse events at the time that each of the alleged misstatements was made. This omission is fatal where, as here, the collection of data may have continued after the last of the purported misstatements and the total increase was a relatively modest 3.8%.⁵

⁵ The plaintiffs cite the FDA's finding that, "[i]n some patients," adverse events "occurred as early as 2 weeks" after taking ponatinib. But the agency's indication that some patients experienced adverse events as early as two weeks into therapy tells us nothing about whether the rate of overall adverse events had increased and, if so, by how much as of the relevant dates.

C. Insider Trading

The plaintiffs seek to bolster their fraud claims with allegations of insider trading by the officer defendants. As an initial matter, while such insider trading may be "probative of scienter," it is not sufficient to establish an inference of scienter on its own. Greebel v. FTP Software, Inc., 194 F.3d 185, 197-98 (1st Cir. 1999).

Here, during the pre-approval period, the complaint alleges that Haluska, Clackson, and Fitzgerald sold "irregular amounts of shares."⁶ These three defendants made their last pre-approval trades on May 2, August 15, and October 1, 2012, respectively. Thus, both Haluska and Clackson ceased pre-approval sales more than a month and a half before the October 5 high-point of ARIAD's share price. Accordingly, the timing of their trades "does not appear very suspicious." Id. at 206. Fitzgerald, the defendant who traded closest to that date, was ARIAD's CFO and the least likely of the three to have been privy to material non-public information about the clinical trials. Moreover, the defendants' trades are readily explainable by the steady increase in ARIAD's share price during the class period, which "create[d]

⁶ We note at the outset that the defendants' use of 10b5-1 trading plans, see 17 C.F.R. § 240.10b5-1(c), is not dispositive in light of the plaintiffs' allegation that those plans were executed after the beginning of the fraudulent scheme. See Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford, 794 F.3d 297, 309 (2d Cir. 2015).

a substantial incentive for holders to sell" regardless of any material non-public information. Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., No. 15-2250, 2016 WL 5682548, at *7 (1st Cir. Oct. 3, 2016).

Plaintiffs' insider trading allegations with respect to the post-approval period do not fare any better. For one thing, the post-approval trades, by definition, occurred after the December 14, 2012 disclosure of the black box warning and the corresponding decline in share price. Additionally, Berger, Fitzgerald, Haluska, and Clackson are all alleged to have entered into the operative 10b5-1 plans within days of that disclosure. At this early date, any information about an undisclosed increase in the rate of serious adverse events would likely have been minimal. Where, as here, the complaint is otherwise devoid of facts supporting the defendants' knowledge of material non-public information, these alleged insider sales are insufficient to salvage the plaintiffs' fraud claims.

IV. Securities Act Claims

The second set of claims allege violations of Section 11 of the Securities Act stemming from a January 2013 common stock offering. The Securities Act "was designed to provide investors with full disclosure of material information concerning public offerings." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 195 (1976). Section 11 advances this goal by creating virtually strict

liability for any "untrue statement" or misleading omission of material fact in a registration statement. 15 U.S.C. § 77k(a).

The right to sue under Section 11 is limited to "any person acquiring such security." Id. Thus, "an action . . . may be maintained only by those who purchase securities that are the direct subject of the prospectus and registration statement." Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 768 n.5 (1st Cir. 2011) (citation omitted). But, in order to state a claim, the plaintiffs "need not have purchased shares in the offering." In re Century Aluminum Co. Sec. Litig., 729 F.3d 1104, 1106 (9th Cir. 2013). Rather, "those who purchased shares in the aftermarket have standing to sue provided they can trace their shares back to the relevant offering." Id. (citing cases); see also, e.g., Krim v. pcOrder.com, Inc., 402 F.3d 489, 495-96 & n.28 (5th Cir. 2005) (citing cases). This requirement is satisfied where, for example, "all of a company's shares have been issued in a single offering under the same registration statement." Century, 729 F.3d at 1106; see also Nomura, 632 F.3d at 766 (involving alleged misstatements in offering documents for "trust certificates representing mortgage-backed securities," each of which was associated with one of two challenged registration statements).

This "statutory standing"⁷ inquiry becomes more complicated where, as here, the company has issued shares under multiple registration statements. In these circumstances, "the plaintiff must prove that [his or] her shares were issued under the allegedly false or misleading registration statement, rather than some other registration statement." Century, 729 F.3d at 1106. The parties disagree about the import of this requirement at the pleading stage. The plaintiffs cite cases for the proposition that mere "general allegations" that their shares are traceable to the offering in question are sufficient to avoid dismissal. The defendants counter that these cases fail to account appropriately for the Supreme Court's decisions in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 556 U.S. 662 (2009). Because we agree with the defendants on this point, we affirm the dismissal of the Section 11 claims.⁸

⁷ The parties refer to this issue as statutory standing, and the district court correctly noted that it does not implicate Article III. See Cooperman v. Individual Inc., 171 F.3d 43, 47 n.3 (1st Cir. 1999). Rather, the defendants' attack on the sufficiency of the complaint is appropriately analyzed under Fed. R. Civ. P. 12(b)(6). See Century, 729 F.3d at 1109.

⁸ The complaint also includes derivative claims under Section 15. See Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1201 n.2 (1st Cir. 1996), superseded by statute on other grounds, 15 U.S.C. § 78u-4(b)(2). Because the Section 11 claims were properly dismissed, we affirm the dismissal of the derivative claims as well.

Twombly teaches that, in order to survive a motion to dismiss, a complaint must include "enough facts to state a claim to relief that is plausible on its face." 550 U.S. at 570. This standard requires more than a mere "formulaic recitation of the elements of a cause of action." Id. at 555; see also Iqbal, 556 U.S. at 681 (holding that "conclusory" allegations are "not entitled to be assumed true"). Accordingly, "allegations that merely parrot the relevant legal standard are disregarded." Manning v. Bos. Med. Ctr. Corp., 725 F.3d 34, 43 (1st Cir. 2013). Moreover, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557).

We find this binding precedent difficult to square with the plaintiffs' contention that general allegations of traceability, without more, are sufficient at the pleading stage. Indeed, traceability is an element of a Section 11 claim. See, e.g., Nomura, 632 F.3d at 768 n.5; Century, 729 F.3d at 1106. And, almost by definition, a general allegation that a plaintiff's shares are traceable to the offering in question is nothing more than a "formulaic recitation" of that element. Twombly, 550 U.S. at 555. Accordingly, we agree with the other circuit that has squarely addressed this issue and hold that such general

allegations alone are not sufficient to avoid dismissal. See Century, 729 F.3d at 1107; see also Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 901 (4th Cir. 2014) (reaching same result under the analogous, though not identical, Section 12(a)(2)).

The question now becomes whether the complaint sets forth sufficient facts to plausibly suggest that the shares purchased by the plaintiffs were issued as part of the January 2013 offering. The plaintiffs could have met this bar by pleading that they "purchased their shares directly in the secondary offering itself." Century, 729 F.3d at 1106. But the complaint expressly precludes this possibility, instead alleging that the named plaintiffs all bought their shares "on the open market." Accordingly, they must plead sufficient facts to suggest that "their shares, although purchased in the aftermarket, can be traced back to the secondary offering." Id. About 15.3 million shares were issued in connection with the January 2013 offering, but an additional 166 million were already outstanding at that time. Moreover, only one of the named plaintiffs bought on the day of the offering and none of them paid the offering price. See Yates, 744 F.3d at 900 n.13 (noting price difference). In these circumstances, the complaint fails to give rise to a plausible inference that the plaintiffs' shares were issued as part of the January 2013 offering. Indeed, the "'obvious alternative explanation' is that they could instead have come from the pool of

previously issued shares." Century, 729 F.3d at 1108 (quoting Twombly, 550 U.S. at 567).⁹

V. Conclusion

For the foregoing reasons we **REVERSE** the district court's dismissal of the Section 10(b), Rule 10b-5, and Section 20(a) claims predicated upon the December 11, 2012 press release. We otherwise **AFFIRM** the dismissal of the fraud claims. Similarly, we **AFFIRM** the dismissal of the Section 11 and Section 15 claims. The case is remanded for further proceedings consistent with this opinion. The parties shall bear their own costs.

⁹ The complaint fails to allege traceability sufficient to state a Section 11 claim for any member of the purported class; accordingly, we need not address the lead plaintiffs' contention that they should be permitted to pursue such a claim on behalf of the class irrespective of their individual statutory standing.