# United States Court of Appeals
## For the First Circuit

No. 21-1657

MYO THANT, Individually and on Behalf of All Others Similarly Situated,

Plaintiff, Appellant,

HEATHER MEHDI,

Plaintiff,

v.

KARYOPHARM THERAPEUTICS INC.; MICHAEL G. KAUFFMAN; SHARON SHACHAM; JUSTIN A. RENZ; MICHAEL F. FALVEY; GAREN G. BOHLIN, MIKAEL DOLSTEN; SCOTT GARLAND; BARRY E. GREENE; MANSOOR RAZA MIRZA; DEEPA R. PAKIANATHAN; KENNETH E. WEG,

Defendants, Appellees.

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

[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Barron, Chief Judge,
Gelpí, Circuit Judge,
and Katzmann,* Judge.

Adam M. Apton, with whom Nicholas I. Porritt, Shannon L.

* Of the United States Court of International Trade, sitting by designation.

Hopkins and Levi & Korsinksy, LLP, were on brief, for appellant.

Michael G. Bongiorno, with whom Peter A. Spaeth, Allyson Slater, Jocelyn M. Keider, Joseph M. Levy, and Wilmer Cutler Pickering Hale and Dorr LLP were on brief, for appellees.

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August 5, 2022

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**KATZMANN, Judge.** Following a decline in the stock price of Karyopharm Therapeutics, Inc., investors (among them, plaintiff-appellant Dr. Myo Thant) filed suit against the company and its corporate officers (together "Karyopharm" or "defendants") alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 18 C.F.R. § 240.10b-5. In relevant part, the complaint alleged that Karyopharm materially misled investors as to the safety and efficacy of Karyopharm's cancer-fighting drug candidate selinexor. The district court dismissed the complaint, finding that plaintiffs failed to adequately plead scienter with respect to defendants' statements about the STORM[1] trial: a single-arm study of the drug selinexor as a treatment for penta-refractory multiple myeloma. Plaintiff-appellant Thant timely appealed.

We now affirm the district court's dismissal on different grounds, concluding that Thant has not plausibly alleged an actionable statement or omission with respect to the STORM trial disclosures.

**I.**

The complaint alleges the following. See Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 30 (1st Cir. 2000)

[1] "Selinexor Treatment of Refractory Myeloma."

(noting that in reviewing a motion to dismiss, we accept all well-pleaded facts in the complaint as true). Karyopharm is a Massachusetts-based biopharmaceutical company that develops and commercializes treatments for cancer, among other serious diseases. One of the drugs in Karyopharm's portfolio is selinexor, a cancer-fighting drug now on the market as a fifth-line treatment (in combination with the steroid dexamethasone) for patients suffering from relapsed or refractory multiple myeloma and acute myeloid leukemia. In laymen's terms, a relapsed or refractory disease is one which has not been eradicated despite treatment, or which has returned at least once following initially successful treatment.

Roughly a decade ago, Karyopharm began conducting clinical tests on selinexor to evaluate its safety and efficacy as a treatment for advanced cancers. The first such test was the Phase 1 KCP-330-001 trial, which treated patients with multiple myeloma who had received at least three prior lines of treatment or therapy without success. The results of this trial were mixed. Patients in the monotherapy arm (treated with selinexor alone) largely saw no improvement in their disease, with only one of fifty-six patients experiencing a "partial response" -- in other words, a decrease in the extent of the patient's cancer. Patients in the combination therapy arm (treated with a combination of selinexor and dexamethasone) had somewhat more positive outcomes, with 8.6%

of patients experiencing a partial response or full remission. Overall, most patients participating in the trial experienced stable or progressive disease. Importantly for the purposes of this case, data from the KCP-330-001 trial evinced a substantial level of toxicity attributable to selinexor.

Phase 2 testing of selinexor began in June 2014 with the SOPRA[2] trial, which treated patients with relapsed or refractory acute myeloid leukemia ("AML") aged sixty or above who were ineligible for standard chemotherapy or transplantation. The SOPRA trial was ultimately terminated before its completion on March 2, 2017 after "Karyopharm 'claimed at that time that it had determined, in concert with SOPRA's Independent Data Safety Monitoring Board, . . . that the study would not reach statistical significance for showing . . . the study's primary endpoint,'" namely, the superiority of selinexor alone as a treatment for AML. Indeed, the data obtained prior to SOPRA's termination showed a comparatively lower overall survival rate for patients treated with selinexor alone versus those receiving standard care (some combination of supportive care, azacitidine, decitabine, and low dose cytosine arabinoside).[3] As with the KCP-330-001 trial,

[2] "Selinexor in Older Patients with Relapsed/Refractory AML."

[3] Azacitidine (also known by the brand name Vidaza) and decitabine (also known by the brand name Dacogen) are cytotoxic drugs which function by altering gene expression to reduce the growth of cancerous cells. PubChem, Decitabine,

SOPRA's initial results also evinced substantial toxicity: 100% of the patients treated with selinexor suffered from adverse events ("AEs") of varying degrees, including some which resulted in death.

After the start of the SOPRA trial (but before its termination) Karyopharm initiated Phase 2b testing with the STORM trial, which was conducted between May 2015 and April 2018. STORM assessed the safety and efficacy of combination treatment with selinexor and dexamethasone in patients with relapsed or refractory myeloma who had received at least three prior lines of treatment or therapy. Unlike SOPRA, the STORM trial was a single-arm study, i.e., one without a control group. Ultimately, STORM resulted in a roughly 25% response rate, but again clearly demonstrated the toxicity of the selinexor dosage administered. In relevant part, 88.6% of patients modified their selinexor dose due to a treatment emergent adverse event ("TEAE") -- the name given to any AE that is not present prior to the initiation of

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https://pubchem.ncbi.nlm.nih.gov/compound/Decitabine (last visited Aug. 3, 2022); PubChem, Azacitidine, https://pubchem.ncbi.nlm.nih.gov/compound/azacitidine (last visited Aug. 3, 2022); Science Direct, Antineoplastic Drugs, https://www.sciencedirect.com/topics/neuroscience/antineoplastic-drugs (last visited Aug. 3, 2022).

Cytosine arabinoside is another cytotoxic drug which, while largely fatal as an intensive treatment, has been determined to induce remission in hematologic cancers when administered in low doses. Science Direct, Cytarabine, https://www.sciencedirect.com/topics/neuroscience/cytarabine (last visited Aug. 3, 2022).

treatment, or that worsens in intensity or frequency following treatment, regardless of cause. Some TEAEs were even fatal, with the study involving eighteen TEAE-related deaths (as well as twenty-two from disease progression).

Roughly a year before the conclusion of the STORM trial, Karyopharm initiated another clinical trial of selinexor: the Phase 3 BOSTON trial, which measured the efficacy of combination treatment with selinexor, dexamethasone, and bortezomib (a chemotherapy drug also known as Velcade) against treatment with dexamethasone and bortezomib alone.[4] Unlike the STORM study, the BOSTON trial was intended to allow evaluation of selinexor in comparison to a control group.

On August 5, 2018, following the conclusion of the STORM trial but prior to the end of the BOSTON trial, Karyopharm submitted a New Drug Application ("NDA") for selinexor to the U.S. Food and Drug Administration ("FDA"). Shortly thereafter, on November 20, 2018, the FDA convened a post mid-cycle review meeting with Karyopharm to discuss outstanding issues that could impact selinexor's approval -- most notably the FDA's concern that the STORM study alone, as a single-arm trial, might not be adequate to

[4] To manage the toxicity of the control drugs, dexamethasone and bortezomib, and better assess the toxicity of selinexor, the study also reduced the dosage of dexamethasone and bortezomib in the selinexor arm by 25% and 40% respectively.

demonstrate selinexor's safety or efficacy vis-à-vis other available treatments.

Subsequently, the FDA arranged for a meeting of its Oncologic Drug Advisory Committee ("ODAC") to take place on February 26, 2019, for an advisory vote on the selinexor NDA. On February 22, 2019, in anticipation of the ODAC meeting, the FDA publicly released a briefing document addressing the results of the STORM study and the merits of the NDA broadly. In relevant part, this briefing document highlighted three primary issues with the submitted study data: first, that the single-arm nature of the STORM trial could not provide conclusive data regarding the efficacy of selinexor; second, that the single-arm nature of the STORM trial could not provide conclusive data regarding the toxicity of selinexor; and finally, that while the STORM trial indicated that lower doses of selinexor were better-tolerated, it did not conclusively establish an optimal dose. In response to the briefing document, Karyopharm's stock price fell from a closing price of $8.97 per share on February 21, 2019, to a closing price of $5.07 per share on February 22. ODAC ultimately voted to delay approval of selinexor pending the results of the BOSTON trial, which caused the stock price to decline further to a low of $4.13 per share on February 28, 2019.

On March 13, 2019, Karyopharm submitted an amendment to its selinexor NDA which proposed to limit the drug's indication to

relapsed or refractory multiple myeloma who had received four, rather than three, prior lines of treatment or therapy -- a population for which there was at the time no approved therapy. Following this amendment and the subsequent submission of the BOSTON trial data, the FDA approved the selinexor NDA on July 2, 2019, roughly eleven months after its initial submission.

**II.**

Two months after the FDA's approval of the selinexor NDA, on September 17, 2019, the initial complaint in this action was filed before the district court. Following the appointment of Dr. Myo Thant ("Thant") as lead plaintiff, the operative complaint was filed on October 22, 2020.

Plaintiff-appellant Thant is a Maryland resident who purchased and retained Karyopharm securities between March 2, 2017, and February 22, 2019. Given the substantial drop in Karyopharm's stock price following the release of the ODAC briefing document in February of 2019, Thant alleges that he and the class of similarly situated investors were harmed by their purchases of Karyopharm stock at prices that were artificially inflated by Karyopharm's materially misleading statements and omissions regarding the safety and efficacy of selinexor.[5] While in his

[5] As stated above, Thant alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), which prohibit the use of manipulative or

complaint, Thant challenged numerous statements concerning all of the clinical trials described, he limits his appeal to Karyopharm's STORM-related statements.

Thant takes issue with Karyopharm's public statements regarding the STORM trial, which he argues were both materially misleading and made with scienter. He points first to the April 30, 2018 press release announcing top-line data from the second half of the STORM trial, which stated in relevant part that:

> Oral selinexor demonstrated a predictable and manageable tolerability profile, with safety results that were consistent with those previously reported from Part I of this study . . . and from other selinexor studies. As anticipated, the most common [AEs] were nausea, vomiting, fatigue and reduced appetite and were primarily low grade and manageable with standard supportive care and/or dose modification.

Thant also highlights statements made to investors by Karyopharm co-founder and CEO Dr. Michael G. Kauffman ("Kauffman") on a May 1, 2018 conference call. Specifically, Thant points to Kauffman's statement that "[t]he success of the STORM study is an important

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deceptive devices and extend liability to individuals, and Securities and Exchange Commission ("SEC") Rule 10b-5, 18 C.F.R. § 240.10b-5, which likewise prohibits the use of manipulative and deceptive devices. While Thant's complaint before the district court also alleged violations of §§ 11 and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77o, those allegations are not at issue on appeal. The only allegations currently before the court are Thant's Sections 10(b) and 20(a) and Rule 10b-5 claims stemming from Karyopharm's public statements concerning the STORM trial.

milestone for Karyopharm[, a]nd these data represent a significant step in establishing the efficacy and safety of selinexor as a new treatment option for patients with myeloma."[6] Thant argues that each of these disclosures "falsely represented to the public" that selinexor trials had consistently yielded positive data, when in fact selinexor "was extremely toxic, not well tolerated, and ineffective." In so representing, Thant contends, Karyopharm artificially inflated its stock price.

To support his allegations, Thant relies not only on the STORM study data itself, but also on a purported history of concealment on the part of Karyopharm executives. The complaint alleges that in August 2016, almost two years before the start of the class period, two high-ranking Karyopharm employees discovered that 353 AEs relating to selinexor (and in part arising from the SOPRA study) had been recorded in Karyopharm's internal records without being reported to the necessary regulatory agencies. Upon

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[6] The complaint also notes Kauffman's statement that:

> This duration of response in the PR group is -- even at this early date, it's already associated with statistically significant improvement in overall survival as compared to the patients who had stable disease or worse. So we do know that patients staying on the drug who have a response will live longer than those that are -- unfortunately do not respond to the drug . . . .

As Thant advances no distinct argument regarding this portion of the press release on appeal, any potential argument is waived.

discovering the omission of these AEs, one of these employees -- Karyopharm's Global Head of Pharmacovigilance and Drug Safety, referred to as "Former Employee 1" or "FE1" -- convened a meeting with Kauffman and other Karyopharm executives. At the meeting, FE1 conveyed that each unreported event would need to undergo a lengthy medical review, and that conducting such review in-house would unfortunately preclude submission of selinexor's NDA by the planned deadline of January 2017. FE1 proposed, as an alternative, that an external clinical research organization be engaged to review the unreported events at the cost of $200,000–$300,000. Kauffman, upset by the delay and cost, insisted that review could be done in-house in time for the January 2017 deadline. FE1 strongly disagreed, and ultimately quit following the meeting.

Shortly after FE1's departure, he was contacted by Karyopharm's Medical Director of Safety ("FE2") who claimed that Ran Frenkel ("Frenkel"), Karyopharm's Chief Development Officer, was pressuring FE2 to falsify study data by characterizing various AEs as unrelated to selinexor. FE2 further indicated that Frenkel identified Dr. Sharon Shacham ("Shacham"), Karyopharm's co-founder, president, and Chief Scientific Officer, as the source of the falsification pressure. FE1 recommended that FE2 carefully record her concerns and report Karyopharm's practices to the FDA.

In January of 2017, two FDA criminal investigators came to FE1's home to ask questions about whether Karyopharm was

falsifying adverse event reports to "jack up the price of the stock." FE1 conveyed to the investigators that Karyopharm was "completely out of compliance" during his tenure, and that FE1 had been concerned that the FDA "would put us on a clinical hold" due to lack of internal controls.

Indeed, as FE1 had predicted, the FDA issued a partial clinical hold on Karyopharm's existing selinexor trials on March 3, 2017, thereby temporarily suspending the ongoing STORM trial. The hold was issued over concerns that Karyopharm had incompletely or erroneously reported study data, including the AEs associated with selinexor. Ultimately, following corrective action by Karyopharm, the clinical hold was fully lifted on April 5, 2017.

Thant also recounts two additional former employee allegations regarding events which took place after the conclusion of the STORM trial (and the start of the class period) in April 2018. FE3 was a consulting physician assisting with the selinexor NDA who was tasked with reviewing and confirming field medical investigators' reports of selinexor AEs. FE3 indicated that Karyopharm's Vice President of Pharmacovigilence, Kumiko Yanase ("Yanase"), regularly questioned FE3's reports and on two occasions asked him to revise his determination that an AE was related to selinexor -- requests he refused. FE4, a clinical research scientist who was employed by Karyopharm following the submission of the selinexor NDA, further reported that

Karyopharm's submissions to the FDA were missing information regarding "preceding" AEs. For example, the data would indicate that a patient experienced sepsis without noting the presence of a prior, less severe infection. Upon reporting this apparent omission to her supervisor, Maitreyi Sharma ("Sharma"), FE4 was informed that Sharma did not agree with FE4's analysis and was concerned that earlier-stage AEs would be treated as separate AEs by the FDA.

**III.**

Ruling on Karyopharm's motion to dismiss for failure to state a claim, the district court found Karyopharm's statement that "selinexor demonstrated a predictable and manageable tolerability profile," made while highlighting the prevalence of low-grade AEs and omitting the high instance of TEAEs and TEAE-related deaths, indeed constituted an arguably incomplete disclosure. Likewise, the district court concluded that Kauffman's description of STORM as successful, and "an important milestone for Karyopharm," likely "skewed" the data such that it "present[ed] a rosy picture" to investors. Accordingly, the court indicated that Thant had plausibly alleged the existence of materially misleading statements.

Nevertheless, the district court found that Thant failed to adequately plead scienter. Noting that the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737

("PSLRA") requires a plaintiff to "state with particularity facts giving rise to a strong inference" of scienter -- i.e., that "the defendant acted with 'either conscious intent to defraud [investors] or a high degree of recklessness,'" – the court concluded that Thant had not pleaded facts supporting such a strong inference. In re Karyopharm Therapeutics Inc., Sec. Litig., 552 F. Supp. 3d 77, 90 (D. Mass. 2021) (alteration in original) (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)). In so finding, the district court highlighted Karyopharm's argument that "no reasonable investor would interpret their statement that selinexor's safety profile was 'predictable' or 'manageable' to mean the drug was benign," in the context of its treatment of a "very ill patient cohort." The district court further concluded that Karyopharm's voluntary disclosure of the 2017 clinical hold, as well as the "high risk of failure" of selinexor (largely due to the risk of side effects), counseled against a finding of scienter. Finally, the district court found that none of the former employee allegations evinced "a desire of defendants to mislead investors" -- and indeed, neither of the accounts relating to events during the class period allege any contact with those Karyopharm officials responsible for the allegedly misleading statements.

Thant now appeals the dismissal of his complaint, arguing that the district court erred by determining Karyopharm's

public statements regarding the STORM trial were not made knowingly or with deliberate recklessness. Karyopharm contends that the district court did not err with respect to scienter and further requests on appeal that the court find the contested statements "were not materially false or misleading in the first instance."

**IV.**

We review de novo whether the complaint meets the heightened pleading requirements of the PSLRA. ACA Fin. Guar. Corp., 512 F.3d at 58 (citing Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002)). Those requirements necessitate that, to state a claim for fraud under Section 10(b) of the Securities Exchange Act of 1934, a complaint must adequately plead "(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." In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017). Only two of these six requirements are now before the court: material misrepresentation and scienter. We conclude that, regardless of whether Thant adequately pleaded facts to support a finding of scienter, he failed to plausibly allege a material misrepresentation sufficient to sustain his complaint. Accordingly, we affirm.

Where, as here, our review is de novo, we are permitted to "affirm on any ground appearing in the record -- including one

that the [district] judge did not rely on." Rivera-Colón v. AT&T Mobility P.R., Inc., 913 F.3d 200, 207 (1st Cir. 2019) (alteration in original) (quoting Lang v. Wal-Mart Stores E., L.P., 813 F.3d 447, 454 (1st Cir. 2016)). This is what Karyopharm now suggests we do, arguing that because "the market could not have misinterpreted [Karyopharm's] statements," Karyopharm "had no duty to disclose [the AE] data, even if [investors] would have wanted to know that information and even if it could have been deemed material," because disclosure is only required where it is necessary to ensure statements are not misleading.

To survive a motion to dismiss under the securities law, a complaint must adequately plead statements that were "misleading as to a material fact" -- neither factor alone is sufficient. Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 238 (1988)). With respect to materiality, it is well established that the requirement is satisfied when there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Id. at 38 (quoting Basic, 485 U.S. at 231–32); see also Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 33 (1st Cir. 2022). It follows that "[i]t is not a material omission to fail to point out information of which the market is already aware." Baron v. Smith, 380 F.3d 49, 57 (1st

Cir. 2004) (citing In re Donald Trump Casino Sec. Litig., 7 F.3d 357, 377 (3d Cir. 1993)).

Even where the materiality requirement is met, a statement or omission must still be misleading. Disclosure of specific information is only required when "necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" Matrixx, 563 U.S. at 44 (alteration in original) (quoting 17 C.F.R. § 240.10b-5(b))). This means that, if a company proactively discloses some facts about its product, it is not thereby obliged to disclose all information that "would be interesting" to potential investors. Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc). Rather, a company must only disclose those facts "that are needed so that what [has been] revealed would not be 'so incomplete as to mislead.'" Id. (quoting SEC v. Tex. Gulf Sulphur Co., 401 F.2d 833, 862 (2d Cir. 1968)).

Finally, we have clearly held that "'upbeat statements of optimism and puffing about [a] company's prospects' are not actionable" and thus cannot constitute material misstatements. Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 32 (1st Cir. 2020) (alteration in original)(quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 207 (1st Cir. 1999)). Such non-actionable statements have included assertions by a robotics company that its device was "a 'breakthrough product,' with 'compelling clinical data'

'demonstrat[ing] the functionality and utilization' of the device," id. at 28 (alteration in original); statements by a software company that it would "lead the market in providing applications and support" and that its "new products have been well received by [its] channel partners and customers," Greebel, 194 F.3d at 190; and statements by a design company that its software was likely "to broaden the number of customers in existing accounts as well as attract new customers," Glassman v. Computervision Corp., 90 F.3d 617, 635 (1st Cir. 1996); among others.

We find that the contested statements are not materially misleading. Beginning with Thant's allegations regarding the May 1, 2018 conference call, we conclude that defendants' statements were non-actionable puffery. Kauffman's assertions that the results of the STORM study constitute "an important milestone for Karyopharm" and represent "a significant step in establishing the efficacy and safety of selinexor as a new treatment option for patients with myeloma," are no more actionable misstatements than claims made by the defendant in Yan v. ReWalk Robotics Ltd., 973 F.3d 22 (1st Cir. 2020), that its high-risk robotic exoskeleton constituted a scientific "breakthrough" supported by "compelling clinical data." 973 F.3d at 28. Such vague optimism about a product's future, even when touting "successful" or "compelling" clinical support, cannot constitute a material misstatement for

purposes of the pleading requirements set by the PSLRA. We thus conclude that Thant has failed to allege a materially misleading statement sufficient to survive a motion to dismiss with respect to the May 1, 2018 conference call.

Proceeding to the April 30, 2018 press release, we agree with defendants (and indeed with the district court) that "no reasonable investor would interpret [Karyopharm's] statement that selinexor's safety profile was 'predictable' and 'manageable' to mean the drug was benign." In re Karyopharm, 552 F. Supp. 3d at 90–91. Accordingly, we conclude that the STORM press release was likewise not materially misleading.

As a threshold matter, we note that Thant's claim (both before the district court and on appeal) is that the April 30, 2018 press release was materially misleading because it omitted known information regarding the serious risks of selinexor treatment. Specifically, Thant notes that

> when [Karyopharm] represented that "selinexor demonstrated a predictable and manageable tolerability profile" and that "nausea, vomiting, fatigue and reduced appetite" were the most common adverse events, [it] already knew that "100% of the enrolled patients experienced [AEs], nearly 60% experienced a severe [AE], more than 25% of patients permanently discontinued the drug due to its side effects and approximately 18 on-study deaths were attributed to it."

He argues that sharing this information with investors would have "significantly altered the 'total mix' of information . . . available" such that its omission was materially misleading.

Matrixx, 563 U.S. at 38 (quoting Basic, 485 U.S. at 231–32). Thant does not claim that the information provided regarding the "most common AEs" was itself materially misleading, nor does he claim that knowledge of additional common AEs would also have significantly altered the information available to investors. Thus, there is no argument before us that omission or misstatement of the "most common" AEs rendered the STORM press release materially misleading.[7]

To evaluate whether Karyopharm's omission of data regarding the prevalence and severity of AEs was materially misleading, we begin with the context of the STORM trial. Selinexor was undergoing clinical testing primarily as a treatment for relapsed or refractory multiple myeloma, a disease which Karyopharm explicitly acknowledged in public filings typically results in "nearly all patients . . . eventually relaps[ing] and

[7] We note that, while the press release states that "the most common [AEs] were nausea, vomiting, fatigue and reduced appetite" and "[t]he most common hematologic AEs were Grade ≥3 cytopenias" this appears to diverge from the data presented elsewhere. The ODAC briefing document indicates that the most common AEs included not only fatigue (79.7% of patients), nausea (69.9% of patients), and reduced appetite (53.7% of patients), but also hematologic AEs thrombocytopenia (71.5% of patients) and anemia (65.9% of patients). In any case, Thant does not contend that Karyopharm's account of the most common selinexor AEs was materially misleading. We thus conclude that because Thant did not make any specific allegations as to why the omission of AEs more common than those listed would materially mislead investors, any claim predicated on the "most common AEs" portion of the STORM press release should be dismissed.

succumb[ing] to their disease." Not only that, but the latter half of the STORM trial specifically focused on treatment of "heavily pretreated patients with penta-refractory myeloma" -- i.e., patients whose cancer had continued to progress despite extensive and varied treatment and who were ultimately left with no other medical options. It is hardly surprising, then, that the "positive top-line data" announced in Karyopharm's STORM press release reflects a median response duration of only 4.4 months in those patients for whom selinexor was effective. These disclosures are ample evidence that the patients participating in the STORM trial were, as Thant himself notes, "very sick patients" pursuing their "last chance" for survival.

Likewise, Karyopharm proactively and regularly informed investors, through Form 10-Ks issued both before and during the class period, that treatment with selinexor had resulted in "serious" AEs in at least a "small percentage" of patients. The 10-Ks filed in March of 2016, 2017, and 2018, each clarify that such serious AEs are those which "result in death, are life threatening, require hospitalization or prolonging of hospitalization, or cause a significant and permanent disruption of normal life functions." Each report further states that "as a result of these adverse events or further safety or toxicity issues . . . we may not receive approval to market any drug candidates." Finally, Karyopharm notes in each 10-K that "[t]he FDA . . . may

disagree with our or our clinical trial investigators' interpretation of data from clinical trials and the conclusion by us or our clinical trial investigators that a serious adverse effect or unacceptable side effect was not drug-related."

Because it is "not a material omission to fail to point out information of which the market is already aware," Thant has not plausibly alleged a material omission with respect to the STORM press release. Baron, 380 F.3d at 57. Any investor reading that selinexor demonstrated a "predictable and manageable tolerability profile, with safety results that were consistent with those previously reported" had also been informed that (1) the STORM trial administered selinexor to severely ill patients facing a real risk of death from multiple myeloma; (2) selinexor had consistently precipitated serious AEs in at least a "small percentage" of patients treated across prior studies; and (3) any assessment by Karyopharm regarding the prevalence or acceptability of serious AEs was in no way a guarantee that the FDA would have a similar view of the safety profile of selinexor. Given this background information, it is difficult to imagine that any investor would read the defendants' statements that Karyopharm had a "predictable," "manageable," and "consistent" tolerability

profile to indicate that selinexor was benign, or that the FDA would find it so.

Even if Thant had plausibly alleged a material omission with respect to the April 30, 2018 press release, he has not alleged that such omission was misleading. He argues, citing In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744 (1st Cir. 2016), that it was "'misleading for [Karyopharm] to express optimism' about the STORM-related data 'after learning [about selinexor's toxicity].'" However, this case is not Ariad.

In Ariad, the eponymous pharmaceutical company submitted a proposed label for its candidate drug ponatinib to the FDA. Despite that label being rejected, and ARIAD being directly informed by the FDA the rejection was due to "inadequate safety disclosures" regarding the risk of severe cardiovascular events, ARIAD's executives publicly "express[ed] optimism about ponatinib's chances for approval with a 'favorable label.'" Ariad, 842 F.3d at 753. At the same time as it elided the FDA's outright rejection of the proposed label, ARIAD publicly identified "pancreatitis as 'the most prevalent' serious adverse event (occurring in 5% of patients) and noted 'low rates of cardiovascular issues'" in patients taking ponatinib. Id. In reality the most prevalent serious AEs were cardiovascular, occurring in 8% of patients. Id. It is undoubtedly misleading for a pharmaceutical company to, as ARIAD did, fail to disclose

material communications with the FDA and overtly mischaracterize the prevalence of [AEs].

Here, on the other hand, Karyopharm neither failed to disclose FDA concerns nor falsely omitted selinexor's most-prevalent risks. While the press release indicated that Karyopharm was in communication with the FDA, it expressly noted that "there can be no guarantee that . . . any feedback from regulatory authorities will ultimately lead to the approval of selinexor." Similarly, Karyopharm proactively couched its optimism regarding the forthcoming NDA by noting that "accelerated approval," as it was seeking for selinexor, "carries a high regulatory threshold." In addition, there is no indication that Karyopharm mischaracterized the STORM data by stating that "nausea, vomiting, fatigue and reduced appetite" were the "most common adverse events," without mention of specific serious AEs. Rather, the FDA's independent evaluation of the STORM data seems to bear out Karyopharm's statement, indicating that the most common non-hematologic AEs (fatigue, nausea, appetite loss, weight loss, and various digestive issues) occurred in a minimum of 37.4% of patients, while the most common serious AE (pneumonia) occurred in only 11.4% of patients.

Although investors may have been interested in the specific serious AEs experienced by STORM trial participants, we have conclusively established that a company is not, by virtue of

making some disclosures about its products, obligated to disclose all potentially interesting information. Backman, 910 F.2d at 16. While Thant may have wished to know more about the total landscape of AEs associated with selinexor, that alone is not enough to render Karyopharm's disclosures materially misleading. Nor does Karyopharm's decision not to include data on the prevalence of serious AEs in its STORM press release rise to the level the misstatements and omissions in Ariad.

Given that Thant has thus not plausibly alleged a material misstatement with respect to the May 1, 2018 conference call or the April 30, 2018 press release, his associated Section 10(b) claim must be dismissed. Likewise, he has not alleged a materially misleading statement sufficient to sustain a claim pursuant to SEC Rule 10b-5. With the dismissal of his Section 10(b) claim, Thant's Section 20(a) claim necessarily fails as well, because he has not stated an underlying violation of the Securities Exchange Act of 1934. See In re Biogen, 857 F.3d at 44–45 (citing ACA Fin. Guar. Corp., 512 F.3d at 67–68). Having determined that dismissal is appropriate, we need not examine Thant's arguments with respect to scienter.

**CONCLUSION**

For the foregoing reasons, the district court's dismissal of Thant's second amended complaint for failure to state a claim is **affirmed.**