United States Court of Appeals
For the First Circuit

No. 19-1964

TIM KARTH,

Plaintiff, Appellant,

ABRAHAM KISWANI; RICHARD J. ERICKSON; RICHARD B. KING, JR.; TERRELL JACKSON,

Plaintiffs,

v.

KERYX BIOPHARMACEUTICALS, INC.; RON BENTSUR; SCOTT A. HOLMES; GREGORY P. MADISON; JAMES OLIVIERO,

Defendants, Appellees.

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

[Hon. Denise J. Casper, U.S. District Judge]

Before

Thompson, Lipez, and Kayatta,
Circuit Judges.

Jeffrey Craig Block, with whom Jacob A. Walker, Nathaniel Silver, and Block & Leviton LLP were on brief, for appellant.

Laurence Adam Schoen, with whom John F. Sylvia, Geoffrey A. Friedman, and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. were on brief, for appellees.

July 9, 2021
[REDACTED OPINION]*

* The full version of this opinion was filed on June 21, 2021, and remains on file, under seal, in the Clerk's Office.

THOMPSON, Circuit Judge. Before us on appeal is a dispute between Tim Karth, an investor who lost money when he bought stock that saw its value plummet soon after that purchase, and Keryx Biopharmaceuticals, Inc., and its executives, all of whom allegedly swindled Karth out of his hard-earned cash by misleading him about the likelihood that Keryx would be able to continue to meet demand for its only drug product. Though, at various points, the case contained a myriad of claims and experienced a long procedural history, the parties agree that the entirety of the appeal is resolved by addressing one question: did Keryx sufficiently warn investors about the vulnerability of its manufacturing infrastructure so that Karth knew of the investment risks when he purchased his shares? The district court answered that question in the affirmative and entered judgment for the defendants, denied Karth's motion for class certification, and denied Karth's motion to file a third amended complaint. Reviewing the case with fresh eyes, we affirm.

BACKGROUND

We recite the alleged facts pertinent to our inquiry as contained in Karth's complaint and attachments incorporated therein in the light most favorable to the non-movant, Karth. See Curran v. Cousins, 509 F.3d 36, 43-44 (1st Cir. 2007). Karth's proposed class consists of anyone who purchased Keryx stock from May 8, 2013, through August 1, 2016. Karth himself purchased Keryx

stock at the end of that class period, on July 19, 2016.[1] Accordingly, the following recitation of the facts is limited to occurrences during the purported class period, with a particular focus on the events of 2016, the year of Karth's stock purchase and Keryx's supply shortage. We set forth the facts chronologically, interspersing information about manufacturing difficulties with information Keryx made known to the public.

Keryx's Leadership and Manufacturing Process

At all relevant times, Keryx was a Boston-based biopharmaceutical company. The four individual defendants served in different corporate roles. Ron Bentsur was Keryx's CEO. Gregory P. Madison was Keryx's COO starting February of 2014 and took over for Bentsur as CEO at the end of April of 2015. James Oliviero served as CFO for Keryx from May of 2003 until July of 2015, when he was replaced by Scott A. Holmes.

During the proposed class period, Keryx commenced production and sale of its only product, a drug named Auryxia. There were two steps in the Auryxia production process. Step one was manufacturing the active pharmaceutical ingredient ("API") and

[1] Karth's First Amended Complaint (the operative pleading at the time the district court granted judgment for the defendants) pleads that the class period ends on August 1, 2016, but his proposed Third Amended Complaint alleges a class period ending on July 29, 2016, or July 31, 2016. We utilize the August 1, 2016, date because that date seems to be the date he cites most consistently, but the outcome would not be altered by the class period ending on any of Karth's listed dates.

step two was converting the API into its finished tablet form. The tablet, when prescribed by a doctor, was used to treat kidney disease. Keryx lacked the ability to complete any manufacturing itself and relied upon third-party contractors for each step of the process. Keryx appears to have enlisted several first-step manufacturers to produce API. As for step two, during the relevant time frame, Keryx only contracted with Norwich Pharmaceuticals, Inc. ("Norwich"), whose principal place of business is Norwich, New York, to complete the process of converting the API into the final product, tablets of Auryxia.

The Early Days: 2013-2015

On May 8, 2013, the first day of Karth's proposed class period, Keryx released a 10-Q form[2] that warned investors of the following risk:

> We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully manufacture and test our drug candidate, our business will be harmed. We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug candidate for use in clinical trials and for future sales. We may not be able to enter into future contract agreements with

[2] The SEC requires public companies to file a comprehensive report about their financial performance, called a 10-Q, at the end of the first three quarters of each fiscal year. 17 C.F.R. § 249.308a.

> these third[]parties on terms acceptable to us, if at all. (Emphases added.)

Beginning in 2014, Norwich experienced problems with the process of converting API into Auryxia tablets. In May, one API contractor asked Keryx to "quarantine" the API that company had produced pending the outcome of a quality control investigation. In June, Norwich notified Keryx that it "rejected" two batches of Auryxia due to contamination found in a tablet. In July, in response to those reports, Keryx instructed Norwich to stop production, but ordered it to resume the next day, which it did.

Shortly after Keryx began navigating these manufacturing glitches, it was also preparing to meet with Food and Drug Administration ("FDA") officials. To that end Keryx enlisted the help of a consultant, Parexel International, to "assess the readiness [of Norwich] in preparation for an FDA pre-approval inspection." Parexel's work, which took place on August 14 and 15, 2014, consisted of a "conference room review of documentation available relative to the production and controls [of Auryxia] that would likely be reviewed during an FDA inspection." Parexel did not visit Norwich's production facilities. Once it completed its assessment, it sent Bentsur a report on August 22. In it, Parexel found that Norwich had the "appropriate facilities and expertise to meet the needs of Keryx," but warned that Norwich was employing an uncommon system for validating the quality of each

step of the production. Given Norwich's approach, the Parexel Report warned that "[i]t has not been demonstrated that the manufacturing process will consistently produce product that meet final specifications."

The FDA approved Auryxia for commercial sales in September of 2014 and in December of 2014, sales began. At that time, the company had enough supply to meet patient demand. Nevertheless, at a board of directors meeting, directors were advised that investors had expressed disappointment that doctors were not prescribing the drug at a high enough rate to make investing in Keryx sufficiently profitable.

Two thousand and fifteen brought a couple of manufacturing developments. One of the API manufacturers had to discard approximately one-third of the API it produced because of quality issues. API problems then caused batches of product produced at Norwich to fail to meet quality standards, which caused production to halt. By October of 2015, however, production had so outpaced sales that Keryx had "too much inventory" and planned to destroy up to 1,632 bottles of Auryxia before their expiration date in March of 2016 if sales didn't pick up. In December of 2015, Keryx provided its board with an update on the company's financial posture. Of import, it learned that the company had an inventory of 14,000 bottles for commercial sale and more than

18,000 bottles for patient samples.[3] Additionally, the board learned that Keryx had to pay a contractual penalty of $2.6 million to Norwich because Keryx did not sell enough Auryxia to utilize Norwich's full production capacity. During this same meeting, the board discussed the company's draft five-year plan. One presenter (who was not clearly identified in the record) reported to the board about risks related to the company's sale of Auryxia. Among those risks, the presenter identified that solely contracting with Norwich for step two manufacturing posed a risk of a "[s]upply disruption" and a "[l]oss of credibility with customers" and characterized the "probability" of that risk materializing as "medium." Because of this risk, the draft five-year plan contained several "high" priorities, one of which was to contract with additional second-step manufacturers.

Publicly, Keryx made written disclosures relevant to Karth's claims. Through the end of 2015, whenever it informed investors of the risks to the company's bottom line, Keryx used the plural term "third parties" to characterize the number of outside manufacturers responsible for producing Auryxia, just as it had at the start of the class period. In its 2015 annual report, Keryx reported on the status of its drug supply, including

[3] Generally, each bottle of Auryxia for commercial sale contained 200 pills and bottles for use as a sample contained 50 or 200 pills.

the value of its inventory of Auryxia pills and raw materials to produce more Auryxia, and included the need to destroy its excess stock before expiration.

The Year of Keryx's Supply Shortage: 2016

In January of 2016, Keryx conducted an internal review and concluded that since sales began in 2014, Norwich had produced ninety-three "batches" of Auryxia and, of those, five were rejected for "varying reasons." When February rolled around, one Keryx employee sent an internal e-mail on the 16th, describing the company's supply of sample-size bottles of Auryxia as "VERY CRITICAL" because the stock was very low.

February 2016 Disclosure and Concurrent Problems

On February 25, 2016, Keryx issued a press release that declared "the fundamentals of Auryxia are solid" and projected between $31 million and $34 million in Auryxia sales in 2016. The next day, Keryx released its 2015 10-K (what we'll call the "February 2016 Disclosure" from here on out).[4] In it, Keryx reported $10.1 million in net sales of Auryxia in 2015 and warned investors:

> We currently depend on a single supply source for Auryxia drug product. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the

[4] A 10-K is a comprehensive report filed annually by public companies about their financial performance. The report is required by the SEC and is far more detailed than an annual report. 17 C.F.R. § 249.310.

> quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations. (Emphasis added.)

The February 2016 Disclosure also announced that Keryx "believe[d] that [it had] established contract manufacturing relationships for the supply of Auryxia to ensure that [it would] have sufficient material for clinical trials and ongoing commercial sales." That same day, on a conference call with investors, Holmes reiterated the projected 2016 sales figures and reported that Keryx was "encouraged with the solid fundamentals [of] Auryxia."

The record is unclear as to how the sample-size shortage got resolved but by the start of March of 2016, any previous issues had been eliminated because Keryx recorded having a stock of 10,301 sample-size bottles to meet a projected demand of 5,574 bottles.[5] Keryx also began March with 5,688 bottles of Auryxia for commercial sale to meet a projected demand of 4,333 bottles. Keryx's internal projections forecasted that, by the end of the month, Norwich would produce an additional 12,540 bottles of Auryxia for commercial use.

On March 23, 2016, an inspection of some of the API batches Norwich had received from a first-step contractor revealed

[5] Karth suggests that the sample-size bottle supply issue was never resolved, but the Keryx documents attached to Karth's complaint include records of production having resumed by the end of February.

they were contaminated so Norwich halted production to investigate. The probe confirmed that one facility, referred to as a "large batch" facility, was the source of contaminated API. Nonetheless, another facility, referred to as a "small batch" API supplier could still provide Norwich with untainted API for Auryxia production, so it shifted to using that "small batch" facility.[6]

Despite this setback, Keryx's internal forecast at the start of April projected that the company had enough supply to meet commercial demand for the entire month. This apparently proved to be true as Karth complains of no supply interruption in April or May of 2016 and the records attached to the complaint plainly reflect Keryx's supply outpacing demand through August.[7]

April 2016 Disclosure and Concurrent Problems

By April 27, 2016, Norwich had notified Keryx that it had discovered contamination in a batch of API.[8] Norwich

[6] There is nothing in the record that explains the differences between "large batch" and "small batch" facilities. As such, we have no reason to assume (and Karth does not argue) that a "small batch" facility produces a drastically different total amount of API.

[7] At the start of March, Keryx had intended for Norwich to produce 3,300 bottles of Auryxia for commercial sale during the month of April. By the start of April, Keryx increased its projections for Norwich's monthly production to 7,154 bottles. Norwich actually produced 3,920 commercial-use bottles during that month to add to Keryx's existing stock of 6,188 commercial-use bottles. This exceeded April sales of 4,944 bottles.

[8] In the proposed Third Amended Complaint, Karth summarizes an e-mail between two Keryx employees (but not the defendants here)

communicated to Keryx that it had found contamination, but had not yet determined why and stopped production to investigate.

The next day, Keryx announced its financial results for the first quarter of 2016 in a press release, a conference call, and its 10-Q statement. In the 10-Q statement (or the "April 2016 Disclosure," as we'll call it from here), Keryx again warned investors:

> We currently depend on a single supply source for Auryxia drug product. If any of our suppliers, including the source of Auryxia drug product, were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations. (Emphases added.)

On the conference call, Madison told investors that Keryx was "off to a good start" and that the company had "established solid fundamentals for Auryxia, including enhancing brand awareness." Madison further reported that Keryx had expanded its sales force and was "confident in [its] ability to achieve [its] net sales guidance." At the same time, Keryx internally projected that it

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in which those employees discussed Norwich's discovery of contamination and noted Norwich's initial belief that this was "an isolated incident." Karth does not allege that Keryx knew of the contamination problem prior to those employees discussing the problem via e-mail and his allegation, as best we tell, is that at the time of the April 27, 2016, e-mail, Keryx thought Norwich had found contamination and had stopped production to investigate the cause of this problem.

would continue to have sufficient stock to meet upcoming demand so long as some production occurred, even with a projected increase in sales.

The April 27, 2016, API issue at Norwich proved to not be an "isolated incident" as first thought. The production stoppage continued through May but was finally resolved and Norwich planned to resume production on June 1, 2016. On May 24, 2016, Keryx internally reviewed the potential for a supply shortage and concluded that there would be no shortage if Norwich could adhere to the planned schedule for restoration. However, if Norwich experienced additional production issues, Keryx predicted its supply of Auryxia would run out on June 19, 2016. Norwich was able to resume production as planned and continued to do so, apparently without incident, into July. Accordingly, Keryx experienced no supply shortages in June or July of 2016.

Summer 2016 Production Problems

Notwithstanding the adequacy of the actual Auryxia supply, July did usher in more production headaches. On July 12, 2016, Norwich notified Keryx that it observed a structural problem with some Auryxia tablets during one step of the manufacturing process. An investigation followed but production did not stop. On July 22, Madison informed Keryx's board that Norwich's current production run was proceeding without issue and that production appeared to be on track for the next planned shipment of Auryxia.

Norwich continued producing Auryxia until July 26, 2016, when it again discovered the same structural problem during a different step of the manufacturing process. Norwich then halted production and commenced an exploration of the source of the structural problem.

Once drug production stopped, Keryx estimated it would run out of its Auryxia supply in one to two weeks if nothing changed. Keryx wrote a letter to the FDA explaining as much and describing the circumstances that led to this impending shortage. Keryx reported that two problems with API in the Spring of 2016 had "constrained supply" but Keryx and Norwich had worked together to correct and prevent the repetition of those API problems. The structural problem that arose for the first time in July of 2016 presented a different issue. Because neither Norwich nor Keryx had as yet identified its cause, they did not then have a solution.[9] Meanwhile, on July 19, 2016, Karth enters the scene: he purchased his Keryx stock. As of that date, Keryx had not released any information to the public about these July production setbacks.

The Supply Shortage

With the manufacturing problems unresolved, on August 1, 2016, Keryx issued a press release withdrawing its 2016 financial

[9] Keryx requested that the FDA expedite approval of an alternative drug supplier or permit Keryx to use the sample-size bottles to meet patient needs. The record does not contain the FDA's response.

projections and characterizing an Auryxia supply interruption as "imminent" due to "a production-related issue . . . at its contract manufacturer." On a call with investors that same day, Madison explained that Norwich "[had] been successfully producing commercial batches for approximately two years" and that "in [the] past few months, [Norwich] began experiencing difficulties converting [API] to finish[ed] drug product." Madison further explained that, prior to that impending shortage, Keryx "had been managing supply levels efficiently even with increased demand . . . in the second quarter." Keryx's stock value decreased thirty-six percent.

Karth Sues for Securities Fraud

From Karth's perspective as spelled out in his complaint, Keryx and the individual defendants knew that the company only employed a single manufacturer, Norwich, and that relying solely on Norwich for the second step of production created a much greater risk of a supply interruption than Keryx admitted to investors. Keryx's inadequate disclosures about its manufacturing defects, says Karth, amounted to securities fraud. Accordingly, Karth sued Keryx and the individual defendants for a violation of §§ 10(b), 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Securities Exchange Commission Rule 10b-5, 17 CFR § 240.10b-5. As a reminder, Karth brought the case as a class action with a putative class of

investors who purchased Keryx stock between May 8, 2013, the day Keryx first published a risk disclosure claiming, as Karth views it, to have more than one second-step manufacturer, and August 1, 2016, the day Keryx announced an interruption of its supply of Auryxia.

After litigation and quite a bit of discovery, the defendants moved for judgment on the pleadings. The defendants characterized the February and April 2016 Disclosures as "corrective disclosures" and argued that, even if Keryx had misled investors about the number of third-party manufacturers and the appurtenant risk in earlier disclosures, those misrepresentations were clearly corrected in February and April of 2016.[10] So, the argument goes, when Karth purchased Keryx stock in July of 2016, he was fully informed about Keryx's single-manufacturer process and the investment's resultant risk. Therefore, Keryx's statements were not misleading when Karth purchased his stock. Karth, naturally, disagreed and contended that Keryx's risk disclosures from May 8, 2013, onward misled investors into believing that the company employed multiple second-step manufacturers when, in reality, it only contracted with Norwich. And while the February and April 2016 Disclosures may have

[10] To remind, each of those disclosures included the following statement: "We currently depend on a single supply source for Auryxia drug product." (Emphasis added.)

accurately quantified the number of second-step manufacturers as one, each undersold the true degree of investment risk because Keryx knew that Norwich was having production problems when it released those disclosures. As a result, Karth alleged, investors purchased Keryx stock without appreciating the fragility of its manufacturing infrastructure and the precarious nature of its ability to consistently turn a profit. Therefore, he argues, Keryx's August 1, 2016, revelation that it only contracted with one second-step manufacturer, who was struggling to meet demand, caused the stock price to precipitously drop. In addition to opposing the defendants' motion, Karth moved for class certification and to file a Third Amended Complaint (his motion to file a second amended complaint having already been denied). The proposed Third Amended Complaint relied on many of the same documents as the operative complaint and beefed up the allegations regarding the defendants' knowledge of Keryx's manufacturing infrastructure struggles. These augmentations, Karth claimed, were enough to demonstrate that the February and April 2016 Disclosures were insufficient.

When analyzing all of the pending motions, the district court assumed, without deciding, that Keryx's risk disclosures issued prior to February of 2016 were misleading but held that the February and April 2016 Disclosures cured any prior misrepresentations because each accurately stated that Keryx only

employed one manufacturer, Norwich, for the second step of the production process.[11] Since Karth purchased his stock in July of 2016, after Keryx published both curative disclosures, the district court held that Karth could not plead any relationship between his own financial loss and the defendants' prior alleged misrepresentations or omissions.

With the "corrective disclosures" at the core of its reasoning, the district court issued an omnibus order, denying both of Karth's motions and allowing the defendants' motion for judgment on the pleadings. Specifically, the district court denied Karth's motion for class certification because it found Karth to be an atypical and inadequate class representative, reasoning that Karth's claims would be too different from the claims of any potential class members who purchased stock prior to the release of the February and April 2016 Disclosures. The district court allowed the defendants' motion for judgment on the pleadings because Karth could not plead that he relied upon misleading statements when he purchased his stock. Finally, citing futility, the district court denied Karth's motion to file a Third Amended

[11] Early in the litigation, the defendants moved to dismiss, arguing, among other things, that the plural "third-party manufacturers" language could refer to Keryx's multiple first-step manufacturers and was therefore not misleading. For reasons that need not be detailed here, the district court did not allow the defendants' motion on these grounds and neither side wrestles with that contention before us.

Complaint because nothing in the proposed Third Amended Complaint changed the court's conclusion that the February and April 2016 Disclosures cured any earlier misrepresentations. After resolving each of those motions, the district court entered judgment for the defendants. Karth timely appealed.

OUR TAKE

Karth's notice of appeal lists all three decisions of the district court as the orders he wants reversed. Typically, we would review each decision thoroughly, likely beginning our analysis by reviewing whether the district court erred in entering judgment for the defendants on Karth's First Amended Complaint and then turning to questions of class certification and the proposed Third Amended Complaint. However, Karth appears to be as dissatisfied with his First Amended Complaint as the district court was because he makes no argument here that the district court's grant of judgment on that pleading was erroneous. Karth also does not contend that the motion for class certification, which was analyzed based upon the allegations in the First Amended Complaint, should have been granted. Rather, Karth is solely interested in his case moving forward via the proposed Third Amended Complaint. To that end, his only request for relief is that we declare the February and April 2016 Disclosures to be "misleading" and remand the case to the district court to proceed with the Third Amended

Complaint.[12] We accept Karth's invitation to focus on the proposed Third Amended Complaint and freshly evaluate whether the district court properly denied the motion to amend or whether the proposed Third Amended Complaint does indeed state a claim.

Standard of Review and Analysis

Where the district court's denial of a motion to amend is based on the legal conclusion that the proposed amended complaint fails to state a claim, we review that decision de novo. D'Agostino v. ev3, Inc., 845 F.3d 1, 6 (1st Cir. 2016). Where, as here, there has been considerable written discovery (Karth calls it "significant"), we "look more closely at the factual allegations to see if they support the legal conclusions pled." Glassman v. Computervision Corp., 90 F.3d 617, 628 (1st Cir. 1996) (evaluating proposed amended complaint in securities fraud action after "three years of litigation and full discovery"). In conducting our de novo review, "we assume as true the raw facts as alleged in the

[12] Lest we think Karth believes his First Amended Complaint does state a claim, the defendants note in their brief that Karth offers us no reason to vacate the judgment on the pleadings or reverse the motion for class certification. Karth, for his part, does not bother to dispute this waiver argument in his reply brief. Seeing no need to dig any deeper, we deem any challenges to the district court's decisions, other than to the denial of the motion to amend, waived and, consequently, affirm across the board. United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[T]he settled appellate rule [is] that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

[proposed Third Amended Complaint] and draw reasonable inferences in favor of [Karth]." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012). We "may supplement the facts contained in the pleadings by considering documents fairly incorporated therein." R.G. Fin. Corp. v. Vegara-Nuñez, 446 F.3d 178, 182 (1st Cir. 2006). There is no one-size-fits-all way of analyzing securities fraud cases; rather, we take a "'fact-specific approach' that proceeds case by case." In re Cabletron Sys., Inc., 311 F.3d 11, 38 (1st Cir. 2002). All of this is to say that we evaluate all facts in the complaint and the incorporated documents to determine whether Karth's proposed Third Amended Complaint states a claim.

The Private Securities Litigation Reform Act ("PSLRA") plays an important role in our review. The PSLRA was "enacted 'to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims.'" In re Bos. Sci. Corp. Sec. Litig., 686 F.3d at 29–30 (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007)). To effectuate that goal, the PSLRA requires a plaintiff to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, [and to] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b); see In re Bos. Sci. Corp. Sec. Litig., 686 F.3d at 30 ("Taken

together, the [PSLRA] requirements make it easier to identify the issues and to dismiss flawed complaints at the complaint stage."). "[A]lthough 'the PSLRA does not require plaintiffs to plead evidence . . . a significant amount of "meat" is needed on the "bones" of the complaint.'" Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 455 (1st Cir. 2017) (quoting Hill v. Gozani, 638 F.3d 40, 56 (1st Cir. 2011)).

The Securities Exchange Act

Section 10(b) of the Securities Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). The Commission has promulgated such a regulation, making it illegal to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 CFR § 240.10b-5(b). Taken together, this means that a successful securities fraud complaint will allege the following six elements: "(1) a material misrepresentation or omission by the defendant[s]; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon

the misrepresentation or omission; (5) economic loss; and (6) loss causation." Amgen Inc. v. Conn. Ret. Plans & Tr. Funds, 568 U.S. 455, 460-61 (2013) (citation omitted).[13]

"To establish a material misrepresentation or omission, [Karth] must show that [the] defendants made a materially false or misleading statement or omitted a material fact necessary to make a statement not misleading." Ganem, 845 F.3d at 454 (citation omitted). "[W]hether a statement is misleading depends on the perspective of a reasonable investor." Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1327 (2015). Information is material "if a reasonable investor would have viewed it as 'having significantly altered the total mix of information made available.'" Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008) (quoting Basic, Inc. v. Levinson, 485 U.S. 224, 232 (1988)). We consider the entirety of the relevant facts available at the time of the allegedly misleading statement, not simply the words of the statement itself. See In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 75-77 (1st Cir. 2012). "[I]f an alleged omission involves speculative judgments about future events, materiality will depend

[13] Karth's claim against the individual defendants pursuant to § 20(a) is for each individual's alleged role in violations of § 10(b) and Rule 10b-5. See 15 U.S.C. § 78t. Therefore, if Karth cannot make out a § 10(b) violation, his § 20(a) claim fails as well.

at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity." Hill, 638 F.3d at 57 (alterations adopted) (emphases omitted) (internal quotation marks and citations omitted). We review that "totality" from the perspective of what the defendants knew at the time, meaning "[Karth] may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 62 (1st Cir. 2008) (quoting Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996)).

Karth's Case

Our analysis focuses on the "total mix of information . . . available" to Karth at the time of his stock purchase in July of 2016. See Basic, 485 U.S. at 232. The district court based its decisions upon its conclusion that the February and April 2016 Disclosures cured any prior misrepresentations and the fact that those disclosures (and the concurrent comments to investors) were among the last public statements made by Keryx prior to Karth's purchase.[14] So, those statements are a large part of that

[14] The defendants argue that Karth waived any argument that the February and April 2016 Disclosures were misleading because he did not specifically allege that those disclosures were misleading

"total mix of information" available to Karth at the time of his purchase. See id. Karth concedes that the singular language in each of those risk disclosures resolved any confusion about how many second-step manufacturers Keryx engaged but argues that those risk disclosures were nonetheless misleading because each understated the true risk of solely relying upon Norwich.

This is not our first occasion to consider whether a risk disclosure sufficiently advised investors of possible negative outcomes. Primarily, all agree, two decisions guide our analysis here: Hill v. Gozani, 638 F.3d 40 (1st Cir. 2011) and Tutor Perini Corp. v. Banc of Am. Sec. LLC, 842 F.3d 71 (1st Cir. 2016).

Hill involved a medical device company, NeuroMetrix, whose profits were dependent on doctors purchasing the device and receiving sufficient reimbursement from patients' health insurance carriers. 638 F.3d at 46-49. For various reasons, there were concerns that insurance providers would stop reimbursing physicians for use of NeuroMetrix's product, which would lead to

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in his proposed Third Amended Complaint and the high pleading standard for Karth's claim requires him to specify each allegedly misleading statement. Rather than wade into the nuances of that argument, we address the issue directly because Karth's argument "is wrong on the merits." United States v. Leavitt, 925 F.2d 516, 517 (1st Cir. 1991).

a drop in purchases, and, ultimately, profit.[15] Id. at 50-51. The plaintiffs alleged that, though the company "specifically . . . disclosed" a possibility of that insurance risk materializing, those disclosures were too vague to properly warn investors of what could occur. Id. at 60. We affirmed dismissal, holding that "although knowledgeable employees . . . believed the [insurance reimbursement] strategy was both losing and potentially dangerous, there is simply nothing in the complaint to suggest that . . . the danger posed by the reimbursement strategy was, at the time the statement was made, a near certainty of ruin." Id. at 59 (emphasis added). Considering that, we held that while a generic, formulaic disclosure of risk does not necessarily absolve the speaker of liability, "neither does it create liability simply because it does not disclose, at the level of detail the plaintiffs request

[15] In Hill, NeuroMetrix staff attempted to advise physicians about how to report procedures to insurance companies in ways that maximized the likelihood of reimbursement, but there was internal disagreement about whether that strategy was legal. 638 F.3d at 47-49. NeuroMetrix did warn investors that, if insurance companies denied coverage of the procedures at issue, physicians would be unlikely to purchase the product on a widespread basis. NeuroMetrix presented this risk as something that "may" occur which "could potentially adversely impact [its] future revenues." Id. at 56, 66. When NeuroMetrix made these disclosures, some insurance companies had already declined to reimburse physicians. Id. at 48-49. One employee at NeuroMetrix even began logging all instances where reimbursement was an issue but was ordered to stop so as not to create an obligation for NeuroMetrix to disclose any of this to physicians. Id. at 49.

in retrospect, all of the factors that contribute to the risk assessment." Id. at 60 (emphasis omitted).

In Tutor Perini Corp., the defendant, Banc of America Securities, LLC ("BAS"), serving as the special banking advisor to the plaintiff, Tutor, a giant construction company, recommended investments that were intended to satisfy Tutor's investment priorities of "avoiding risks and illiquidity." 842 F.3d at 76-78. After a few years of guiding Tutor's investment strategies, BAS persuaded Tutor to purchase auction rate securities ("ARS").[16] Id. at 78. Eventually, the ARS market turned sour and BAS knew that the market was on the "brink of collapse." Id. at 88. BAS "knew about an impending collapse" and instructed its own personnel to "protect" the company by encouraging investors to purchase ARS, so that BAS would not be left holding these securities when the market imploded. Id. at 81-83. Following that internal directive, BAS sold quite a bit of ARS to Tutor and at the same time, assured Tutor that it would continue to support ARS auctions, so that Tutor would never be stuck with these investments when it needed cash. Id. at 83. At the height of Tutor's ARS shopping spree, the market

[16] ARS are investment vehicles that are bought and sold at nonpublic auctions and, if an auction fails because there are not enough bids within the applicable parameters, the ARS owner is left holding onto its investment until the next auction. Id. at 77-79. If Tutor wanted to sell its ARS in order to have more cash on hand and auctions for Tutor's ARS were to fail, Tutor would be left illiquid, unable to sell its investment on its preferred timeline. Id.

collapsed entirely (just as BAS knew it would). "Tutor Perini was left holding 'illiquid' investments—its nightmare scenario." Id. at 83.

With each of those ARS sales, BAS had included disclosures that stated, "BAS offers 'no assurances' about the outcome of any auction." Id. at 83. Tutor sued for securities fraud and argued that those warnings, though they technically put Tutor on notice that purchasing ARS was a risk, were insufficient to absolve BAS of liability. Id. We agreed and held that BAS's particular relationship with Tutor required far more than general disclosures. Id. BAS had expressly promised to "provide investment solutions that [met Tutor's] needs by clearly defining the risk/reward of particular securities." Id. at 87 (internal quotation marks omitted). Yet, when BAS saw the risk-to-reward ratio of ARS shifting, it did not say so. Id. Rather, it continued to push ARS on Tutor as if nothing had changed. Id. Considering all of that, we held that BAS "knew (but elected not to disclose) that the ARS market teetered on the brink of collapse when it encouraged Tutor Perini to snatch up more ARS." Id. at 91. Therefore, BAS could not hide behind generic disclosures and, when it communicated the risk of purchasing ARS to Tutor, it had a duty to disclose that the risks had "dramatically changed." Id. at 87.

Each of these cases, at least in their reasoning, invoke the "Grand Canyon" metaphor, where one cannot tell a hiker that a

mere ditch lies up ahead, if the speaker knows the hiker is actually approaching the precipice of the Grand Canyon. See id. at 90. That (non-existent) Grand Canyon in Hill was the "near certainty" (or lack thereof) that insurers would stop covering NeuroMetrix's product and that physicians thereafter would not purchase it. See Hill, 638 F.3d at 59. In Tutor Perini, the Grand Canyon was the meltdown of the ARS market that BAS was so certain was imminent that it pushed ARS onto Tutor to save itself. See Tutor Perini, 842 F.3d at 93. Moreover, BAS knew Tutor's specific financial goals, level of risk tolerance, and precisely what it feared: illiquidity. Id. So, Tutor was more than just a hiker near the Grand Canyon; it was a hiker that had hired BAS as a wilderness guide with the explicit instruction to steer clear of cliffs because of a fear of heights.

Examining Hill and Tutor Perini, as well as other, similar cases, we can understand the contours of what makes a risk so great that it is akin to the Grand Canyon (and therefore a disclosure is misleading if it frames the risk as merely hypothetical) and what makes a situation merely risky (i.e., simply a ditch). A securities fraud defendant is at the edge of the Grand Canyon where the alleged risk had a "near certainty" of causing "financial disaster" to the company. Hill, 638 F.3d at 59-60; accord Tutor Perini, 842 F.3d at 90. Of course, the defendant company must have understood the near certainty of the risk at the

time it made the statements at issue. ACA Fin. Guar. Corp., 512 F.3d at 62. Such knowledge is often evidenced by a company's frenzied, underhanded efforts "to keep the house of cards standing." In re Cabletron Sys., Inc., 311 F.3d at 24. If a company is "desperate[ly]" working to "protect itself" from rapidly approaching harm, then it is at the edge of the Grand Canyon and must warn investors of an imminent cliff. Tutor Perini, 842 F.3d at 88-91. A company must also disclose a relevant risk if that risk had already begun to materialize. See id. at 86-88 (holding defendant company could be liable where warned-of risk was actually occurring, but risk disclosures remained vague and hypothetical); see also Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 986 (9th Cir. 2008) (holding risk disclosure was insufficient where company warned revenue could fall short of projection, but omitted that it had already had its revenue stream "immediately interrupt[ed]" by stop-work orders).

In contrast, a defendant company is merely approaching a ditch where, internally, there was no "widely-accepted certainty of failure" or "comprehensive cover-up." Hill, 638 F.3d at 59. If the company did not "kn[ow] with certainty" that a risk would materialize, it is not necessarily liable for characterizing that risk as a "future risk." Wilson v. Merrill Lynch & Co., Inc., 671 F.3d 120, 130-31 (2d Cir. 2011). This standard does not require a company to be omniscient, even if the company looks foolish in

hindsight for not properly predicting whatever harm befell it. Greenstone v. Cambex Corp., 975 F.2d 22, 25-26 (1st Cir. 1992). As we have said before, "fraud by hindsight" is not enough to sustain a claim. ACA Fin. Guar. Corp., 512 F.3d at 62.

What This Means for Karth

The Grand Canyon in this case, according to Karth, is the "supply interruption" that Keryx announced was imminent on August 1, 2016. According to Karth, Keryx knew it was approaching a cliff and failed to warn investors. Specifically, Karth argues here that the February and April 2016 Disclosures were too general and were misleading because each characterized the risk of a supply interruption as hypothetical when, according to Karth, that disruption was actively occurring. Karth additionally contends that Keryx undersold the true risk of using a single manufacturer by declaring in the February 2016 Disclosure that Keryx had enough contract manufacturers. Karth also calls misleading various press releases and statements made during conference calls in 2016, where Keryx, generally, and Holmes and Madison, individually, touted the "solid fundamentals" of Auryxia and reported that the company was "off to a good start." Reading the allegations in the complaint and attached records in the light most favorable to Karth's case, we conclude that the facts alleged do not indicate that a supply interruption was happening or was even close to a "near certainty." Nor do they indicate a "widely-accepted certainty of failure" at

the time any of Keryx's statements were made. See Hill, 638 F.3d at 59-60.

The February 2016 Disclosure and Concurrent Statements

Karth claims the February 2016 Disclosure and concurrent statements were misleading because none informed investors that Norwich was struggling to produce Auryxia.[17] However, Karth sets forth no facts in his complaint showing that a supply interruption was looming at that time. Indeed, our review of the record shows that in the month prior, Keryx's assessment of its manufacturing protocol demonstrated that over ninety percent of the batches of Auryxia produced at Norwich met all quality standards. Plus, it shows Keryx was having no issues with production of Auryxia for commercial sales and finished February of 2016 with over one thousand commercial-use bottles beyond what the company predicted it needed for the coming month. See id. at 57 (holding that information may not be material if company did not internally predict the event in question would come to pass).

The only production issue that Karth plausibly pleads is that in early February, Norwich was struggling to produce enough

[17] As a reminder, on February 25, 2016, Keryx issued a press release describing Auryxia's "fundamentals [as] solid" and its leadership made similarly positive public statements; and on February 26, 2016, Keryx released the February 2016 Disclosure, which included a disclosure to investors that Keryx was relying on "a single supply source."

sample-size bottles of Auryxia.[18] Yet, Karth does not plead that a supply interruption actually occurred (including of sample-size bottles), that anyone at Keryx thought such an interruption was approaching, or that these production problems impacted Keryx's revenue at all. See Williams v. Globus Med., Inc., 869 F.3d 235, 242-43 (3d Cir. 2017) (holding that, where securities fraud defendant warned of hypothetical risk to revenue, company was not liable for failing to disclose the risk had actually occurred if the risk did not impact revenue). Instead, Keryx understood from historical experience that occasional production stoppages at Norwich had not caused shortages of Auryxia. Recall that in 2014, 2015, and several times in 2016, Norwich stopped production, often due to issues with API produced by first-step manufacturers, and each time, Norwich resumed production before any supply shortage panned out. Those stoppages were apparently so inconsequential that Keryx had an excess stock of 1,632 bottles of Auryxia slated for destruction by March of 2016. Karth pleads no facts suggesting Keryx should have thought, for the first time, that a production stoppage would necessarily yield an uncorrectable supply interruption. See Hill, 638 F.3d at 59 (holding that omitted

[18] Karth pleads that one employee characterized the supply of sample-size bottles as "very critical" but the records of the actual number of sample-size bottles exceeded predicted demand and (after that month ended) actual demand. Karth says nothing about the supply of full-size commercial-use bottles at the time of the February 2016 Disclosure.

information may not be material if the event was unlikely to occur). For the same reasons, Karth has no case based upon the February 25, 2016, public statements. Considering what Keryx and the individual defendants knew at the time, those statements are merely expressions of "past optimism" that Karth may not turn into "fraud by hindsight." See Shaw, 82 F.3d at 1223.

The April 2016 Disclosure and Concurrent Statements

Moving closer to the time of Karth's stock purchase, Karth pleads that for several reasons, the April 2016 Disclosure and concurrent press statements touting Auryxia's viability were inadequate, but as we view it, he sets forth insufficient facts as to why that is so. For instance, Karth characterizes Norwich's production stoppage on March 24, 2016, as yet another ongoing supply interruption which should have caused Keryx to provide heightened risk information to investors in its April disclosures. But Karth's own complaint pleads that Norwich addressed that issue by switching its source of API. Also, our record review shows that just like in February of 2016, Keryx's internal forecast for production in May of 2016, written in the middle of April, projected that the company had enough supply to meet commercial demand for the entire month of May. That prediction came true and Keryx's supply exceeded demand until August. Therefore, at the time the April disclosures were made, it seemed Keryx had solved any production problem before anyone in the company thought the

patient supply of Auryxia was at risk. See Tutor Perini, 842 F.3d at 90 (holding risk disclosures insufficient where company knew with "near certainty" that risk was going to materialize). Karth himself describes the risk as conditional, not impending, alleging that, in March, the defendants "knew that if full production did not resume within April, a supply interruption would occur by mid-May." Appellant's Opening Br. at 31.

In further support of his argument to us that the April 2016 Disclosure is misleading, Karth repeatedly characterizes it as being published "in the middle of a 5-week production stoppage." However, his own complaint and its appended documents tell a very different story. In truth, the earliest Karth alleges that Keryx knew of the problem that yielded a five-week production stoppage was April 27, 2016, and the April 2016 Disclosure was released the next day, far from the middle of a production interruption. Plus, at the time Keryx released the April 2016 Disclosure, Norwich, as we gather from Karth's complaint, had given Keryx no reason to think there was a likely systemic production problem. Compare Wilson, 671 F.3d at 133-34 (affirming dismissal where defendants did not "kn[ow] with certainty" that warned-of risk would occur), with Berson, 527 F.3d at 986 (holding that hypothetical warning was insufficient when defendant company knew that revenue was already impacted at time of disclosure). Even Karth pleads that Keryx "assum[ed] that the Norwich production issues would be

resolved." A risk disclosure is not fraudulent simply because a company makes reasonable assumptions that, in retrospect, prove incorrect. See ACA Fin. Guar. Corp., 512 F.3d at 62.

For that same reason, Keryx's positive public statements about Auryxia in April are just as benign as the statements in February — Keryx's own manufacturer, Norwich, from what we can discern from the record before us, thought this might have been an "isolated incident" and was investigating the issue. See Shaw, 82 F.3d at 1223. Further, at the point of the April 2016 Disclosure and related public statements, Keryx had even more reason than in February of 2016 (when it published the other challenged disclosure) to think that Norwich would rectify any production problems before they impacted supply, because Norwich had successfully done so in February and March. See Tutor Perini, 842 F.3d at 90.

A Few Loose Ends

Karth raises two more arguments that merit some discussion. First, he highlights the Parexel Report from 2014 as evidence that Keryx knew all along that Norwich would have production problems. This does not align with the text of the Report, appended to the complaint. In reality, Parexel, after conducting a "conference room review of documentation" but not visiting Norwich, concluded that Norwich had the "appropriate facilities and expertise to meet the needs of Keryx," but cautioned

that, because of Norwich's uncommon validation system, it "ha[d] not been demonstrated that the manufacturing process w[ould] consistently produce product that [met] final specifications." At best (for Karth's case), the Parexel Report warned Keryx that 1) Norwich's production process was not guaranteed to be flawless and, 2) at least by implication, if Norwich experienced enough production problems, Keryx's bottom line could suffer.[19] This is precisely the risk Keryx warned investors, like Karth, about in the February and April 2016 Disclosures: if Norwich were to "fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, [Keryx] could experience a loss of revenue." Therefore, even accepting Karth's characterization of the 2014 Parexel Report, we do not see how it amounts to any certainty that a 2016 supply interruption was imminent. See Tutor Perini, 842 F.3d at 90.

Second, as to the February and April 2016 Disclosures, Karth's argument that the language was "too boilerplate" simply does not align with text of the disclosures. A disclosure can be insufficient where it does not include any "meaningful cautionary language," but merely warns investors that no results are guaranteed. Lormand v. U.S. Unwired, Inc., 565 F.3d 228, 244-45

[19] If Keryx did not pick that up from the Parexel Report in 2014, it had certainly learned by 2016 that Norwich's work could be inconsistent.

(5th Cir. 2009). In contrast, the disclosures here specifically identify the risk — the use of a single manufacturer who could fail to produce enough Auryxia "to meet market demand" — and explained what that would mean for investors — "a loss of revenue." Relatedly, Karth argues that the risk disclosures should have specifically included the language "supply interruption." It is difficult to see how that particular phrasing would be material to investors, but the synonymous warning that the company might fail "to meet market demand" would not be. See Basic, 485 U.S. at 232 (holding information is material if it would have "significantly altered the total mix of information made available" (internal quotation marks omitted)).

Though it may be a tough pill to swallow, the district court properly denied Karth's motion to amend as futile. Karth's proposed Third Amended Complaint fails to state a claim because the pleadings and attachments, when appropriately scrutinized, fail to show Keryx made material misrepresentations or omissions upon which Karth relied when he purchased Keryx's stock.

WRAP UP

We **affirm** the entry of judgment and award costs to the defendants.