United States Court of Appeals
For the First Circuit

No. 23-1843

SOPHIA ZHOU, individually and on behalf of all others similarly situated,

Plaintiff, Appellant,

NICHOLAS LUONGO, individually and on behalf of all others similarly situated; YICHUN XIE, individually and on behalf of all others similarly situated; GREGORY HATHAWAY, individually and on behalf of all others similarly situated; OSCAR GUZMAN-MARTINEZ, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

DESKTOP METAL, INC.; RIC FULOP; ALI EL-SIBLANI; and MICHAEL JAFAR,

Defendants, Appellees,

JAMES HALEY,

Defendant.

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

[Hon. Indira Talwani, U.S. District Judge]

Before

Gelpí, Montecalvo, and Rikelman,
Circuit Judges.

Lucas E. Gilmore, with whom Steve W. Berman, Kevin K. Green, Raffi Melanson, and Hagens Berman Sobol Shapiro LLP were on brief,

for appellant.

Roman Martinez, with whom Kristin N. Murphy, William J. Trach, Jeff G. Hammel, and Latham & Watkins LLP were on brief, for appellees.

October 28, 2024

RIKELMAN, Circuit Judge. Sophia Zhou and other investors brought a federal securities fraud class action against Desktop Metal, Inc. and several of its corporate officers, following a drop in the price of Desktop Metal's stock in late 2021. The stock lost value after Desktop Metal publicly shared the results of an internal investigation, which uncovered corporate mismanagement and required recall of two key products.

In a thorough opinion, the district court dismissed Zhou's complaint for failure to state a claim. Zhou appeals, contending the court made two mistakes. First, she argues that defendants' motion to dismiss targeted only her material misrepresentations and omissions claim and, therefore, the district court erred in dismissing her entirely separate "scheme liability" claim. Second, she insists that, in any event, she did adequately state a securities fraud claim based on defendants' material misrepresentations and omissions. On de novo review, we conclude that Zhou did not preserve a scheme liability claim and that the district court correctly determined that the complaint failed to plead any materially false or misleading statement or omission. We therefore affirm the district court's ruling.

I. BACKGROUND

A. Relevant Facts

We draw the facts from the complaint, taking the well-pleaded facts as true and construing all reasonable

inferences in Zhou's favor. Lawrence Gen. Hosp. v. Cont'l Cas. Co., 90 F.4th 593, 595 (1st Cir. 2024) (quoting Lanza v. Fin. Indus. Regul. Auth., 953 F.3d 159, 161 (1st Cir. 2020)).

1. Desktop Metal's Acquisition of EnvisionTEC

Desktop Metal is a publicly traded company that specializes in 3D printing. 3D printing does not involve printing per se; instead, it is the process of creating a three-dimensional object layer-by-layer, joining each layer to the layer below it during manufacturing. Defendant Ric Fulop was the Chief Executive Officer ("CEO") of Desktop Metal during the time period at issue in this case.

In February 2021, Desktop Metal acquired EnvisionTEC, Inc., a company specializing in 3D printing solutions for medical, dental, and industrial markets. Defendant Ali El-Siblani was the co-founder and CEO of EnvisionTEC prior to the acquisition. Under the acquisition's terms, El-Siblani became a director of Desktop Metal and remained the CEO of EnvisionTEC, which became a fully owned subsidiary of Desktop Metal.

After acquiring EnvisionTEC, Desktop Metal created a new division, Desktop Health, covering Desktop Metal's medical and dental device portfolio, including EnvisionTEC's dental technology. When Desktop Health was announced on March 15, 2021, Desktop Metal brought on defendant Michael Jafar to serve as Desktop Health's President and CEO.

2. EnvisionTEC's Dental Portfolio

In early 2021, Desktop Metal repeatedly highlighted the advantages of acquiring EnvisionTEC's photopolymer 3D printing technologies, particularly its dental device portfolio. At that time, EnvisionTEC was a leader in photopolymer printing, a 3D printing process that uses light to cure, or harden, liquid photopolymer resin. According to Desktop Metal, EnvisionTEC was poised to become a leader in the dental market as well.

To create its dental products, EnvisionTEC used Digital Light Printing ("DLP"), a process that involves three steps. First, a user sends printing instructions to a 3D printer, which creates the object (e.g., denture teeth and denture bases) using a biocompatible material (typically resin). Second, the user cleans the object to remove excess resin. Third, the user inserts the object into a curing unit, which uses light to harden the object. EnvisionTEC sold -- and now Desktop Metal sells -- all the components of the process: the printers, the biocompatible materials, and the curing units.

At the center of this litigation are two products that were part of Desktop Health/EnvisionTEC's dental portfolio at the time. The first product was really a group of products: EnvisionTEC's proprietary resins used for 3D printing dentures and teeth, specifically Flexcera Smile (for denture teeth) and Flexcera Base (for denture bases). In March 2021, Desktop Metal

applied for 510(k) clearance from the Food and Drug Administration ("FDA") to market the Flexcera products for permanent use by patients. 510(k) clearance refers to a section of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., which permits the FDA to "'clear' a device that is substantially equivalent in safety and effectiveness to an existing approved device and thereby allow the device to be used for the same intended purposes." Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 232 (1st Cir. 2015). On May 12, 2021, Desktop Metal announced that it had received that FDA clearance.

The second product that features in this case is the PCA 4000 curing box, used in the third step of the DLP printing process. In 2021, EnvisionTEC sold the Otoflash curing box, which was considered the gold standard for 3D printed medical devices and which EnvisionTEC purchased from a manufacturer, rebranded, and sold at a markup. EnvisionTEC also manufactured and sold its own line of curing boxes, known as the PCA series. In late 2020 or early 2021, EnvisionTEC began selling the PCA model at issue here: the PCA 4000.

3. The Alleged Fraud Schemes

Zhou alleges that defendants carried out two fraudulent schemes. First, she claims that defendants instructed staff to manufacture Flexcera at facilities that were not registered with the FDA and then conceal that unlawful activity by repackaging the

Flexcera with false labels. Second, Zhou alleges that in spring 2021, defendants marketed their PCA 4000 curing box for use with Flexcera, even though it had not been certified by the FDA for that use.

The first scheme involved the alleged violation of the FDA's establishment registration and labeling requirements. The FDA mandates that owners or operators of establishments involved in the production and distribution of medical devices intended for use in the United States register those establishments with the FDA -- a requirement known as establishment registration. See generally 21 C.F.R. pt. 807. As part of establishment registration, owners or operators must provide information about the medical devices produced at an establishment. See 21 C.F.R. § 807.25. The FDA also requires that medical device labels "specify conspicuously the name and place of business of the manufacturer, packer, or distributor." 21 C.F.R. § 801.1(a). It is unlawful to introduce or deliver for introduction into interstate commerce a device that is "misbranded," see 21 U.S.C. § 331(a), including one that is misbranded because its "labeling is false or misleading," see 21 U.S.C. § 352(a)(1).

In compliance with the establishment registration requirement, EnvisionTEC registered two facilities for the manufacture of medical devices -- a facility in Gladbeck, Germany,

and its U.S. headquarters in Dearborn, Michigan.[1] But, at the time, only the Gladbeck facility was registered to manufacture dental resins specifically. EnvisionTEC also had a facility in Montreal, Canada, which was not registered with the FDA. EnvisionTEC generally manufactured resins that do not require FDA registration at its Canada facility.

In early spring 2021, El-Siblani instructed staff to begin producing the Flexcera resin in Montreal, and in April or May 2021, El-Siblani instructed the head chemist at the Montreal facility to "up his production" of Flexcera resin. Flexcera resin manufactured in Montreal was then shipped to the Michigan facility, where staff repackaged the resin and improperly labeled it "as being of German origin." As a result, Desktop Metal sold non-FDA compliant Flexcera resin from April 2021 through October 2021. According to Zhou, the non-compliant resin made up at least 10% of all Flexcera resin sales during that period.

The second scheme Zhou alleges focuses on the spring 2021 marketing of the PCA 4000 curing box for use with Flexcera. At that time, the FDA had not cleared the PCA 4000 for use with 3D printed medical devices, and Desktop Metal's application for FDA 510(k) clearance of Flexcera had relied on results from Flexcera

[1] Even after Desktop Metal acquired EnvisionTEC, EnvisionTEC's operations continued to operate under the trade name "EnvisionTEC" for purposes of FDA registration.

products cured with the Otoflash, not the PCA 4000. Nonetheless, in March 2021, El-Siblani instructed the sales team to sell the PCA 4000 as the default curing unit for EnvisionTEC dental resins.

The marketing continued even though both employees and customers voiced concerns about Flexcera products cured with the PCA 4000. In a sales team call with El-Siblani, employees questioned whether the PCA 4000 was strong enough to cure Flexcera products and whether the FDA had certified this use of the PCA 4000. El-Siblani instructed the sales team to sell the PCA 4000 over those concerns. Similarly, staff at the German facility found the PCA 4000 was not compatible with curing Flexcera resin during testing, at least at the curing times that Desktop Metal recommended in its instructions to customers. And, customer feedback after Desktop Metal began selling the PCA 4000 indicated that the PCA 4000 was, in fact, not curing Flexcera products sufficiently. Customers complained that Flexcera cured with the PCA 4000 was coming out "gummy." Finally, independent testing revealed issues with the strength of Flexcera products cured with the PCA 4000, which an external researcher reported to Desktop Metal leadership, including Jafar, in an email.

4. The Whistleblower Complaint and Product Recalls

In early November 2021, Desktop Metal employees emailed high-level individuals across various departments of the company, including Human Resources and Operations, with concerns about the

production and bottling of non-FDA-compliant resin. In response, Desktop Metal hired a third party to conduct an independent investigation into "manufacturing and product compliance practices and procedures with respect to a subset of its photopolymer equipment and materials at its EnvisionTEC US LLC facility." Desktop Metal filed a Form 8-K with the Securities and Exchange Commission ("SEC") on November 8, 2021, disclosing the investigation. On the same day, Desktop Metal filed a separate Form 8-K disclosing that El-Siblani had resigned as CEO of EnvisionTEC and as a director of Desktop Metal on November 5, 2021. Desktop Metal's stock price fell about 10% after these disclosures.

A week later, Desktop Metal announced that it had decided to notify the FDA about compliance issues with Flexcera resin and the PCA 4000. After making this announcement on November 15, 2021, its stock price fell again, by about 15%.

Desktop Metal ultimately initiated two recalls with the FDA in January 2022 -- one for the Flexcera Smile resin manufactured from April 1, 2021, to September 15, 2021, and one for PCA 4000 curing units sold to non-industrial users. Desktop Metal also notified direct accounts of EnvisionTEC to "stop utilizing the PCA 4000 to print medical devices made from EnvisionTEC dental resins."

B. Procedural History

This appeal arises from a consolidated class action. After considering competing motions for appointment of lead plaintiff, the district court severed one of the actions, brought by Yichun Xie; appointed Xie as the lead plaintiff of the severed action; and appointed Zhou as the lead plaintiff of the consolidated action. The district court also determined the class period for the Zhou consolidated action would be February 17, 2021, through November 15, 2021.[2]

That brings us to the complaint at issue in this case. In that complaint, Zhou brought securities fraud claims under sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a et seq., and SEC Rule 10b-5, 17 CFR § 240.10b-5. Defendants moved to dismiss the consolidated complaint for failure to state a claim pursuant to the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, and Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. The district court granted the motion to dismiss Zhou's complaint in its entirety. Luongo v. Desktop Metal, Inc., No. 1:21-CV-12099, 2023 WL 6142715, at *1 (D. Mass. Sept. 20, 2023). Zhou timely appealed.[3]

[2] The actions were later re-consolidated for the purpose of pretrial proceedings. But we focus only on Zhou's claims in deciding this appeal.

[3] Because only Zhou appealed, our review is limited to the portions of the district court's order directed at Zhou's claims.

II. STANDARD OF REVIEW

We review de novo a district court's decision to grant a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Lawrence Gen. Hosp., 90 F.4th at 598. Because Zhou brought federal securities fraud claims, several additional legal standards apply. We must evaluate Zhou's complaint to determine whether the allegations of securities fraud have been pled sufficiently to satisfy the requirements of both the PSLRA and Rule 9(b) of the Federal Rules of Civil Procedure. Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011).

As with any motion to dismiss under Rule 12(b)(6), we "accept well-pleaded factual allegations in [Zhou's] complaint as true and view all reasonable inferences in [her] favor." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). We affirm the district court's dismissal if the complaint fails to "allege facts sufficient to demonstrate 'a plausible entitlement to relief.'" Hill, 638 F.3d at 55 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007)).

To state a section 10(b) and Rule 10b-5 violation, Zhou's complaint must allege six elements: (1) a "device, scheme, or artifice" employed to defraud; a material misrepresentation or omission; or an "act, practice, or course of business which operates or would operate as a fraud or deceit upon any person"; (2) scienter, or a wrongful state of mind; (3) a connection with

the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. 17 C.F.R. § 240.10b-5; ACA Fin. Guar., 512 F.3d at 58. The district court was bound to dismiss Zhou's complaint if she failed to allege any one of these elements.

Further, under Rule 9(b), as with all fraud claims, Zhou is required to plead the circumstances of the securities fraud with particularity. Hill, 638 F.3d at 55. And, under the PSLRA, she must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." ACA Fin. Guar., 512 F.3d at 58 (modification in original) (quoting 15 U.S.C. § 78u-4(b)(1)).

"The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter." Id. "A complaint will survive a motion to dismiss only if it states with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" Abiomed, 778 F.3d at 240 (quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)).

III. DISCUSSION

A. Scheme Liability

We turn first to whether Zhou has preserved a scheme liability claim. According to Zhou, she adequately argued to the

district court that defendants' motion to dismiss failed to address her separate scheme liability claim under Rule 10b-5. We disagree.

"It is hornbook law that theories not raised squarely in the district court cannot be surfaced for the first time on appeal." McCoy v. Mass. Inst. of Tech., 950 F.2d 13, 22 (1st Cir. 1991). To preserve a claim for appeal, a party cannot "merely . . . mention a possible argument in the most skeletal way" to the district court -- parties have the duty to spell out their arguments "squarely and distinctly." United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990); Rivera-Gomez v. de Castro, 843 F.2d 631, 635 (1st Cir. 1988). We determine as a matter of law whether a party has sufficiently developed its claim before the district court, such that the claim is preserved for appeal. See, e.g., McCoy, 950 F.2d at 22; Iverson v. City of Bos., 452 F.3d 94, 102 (1st Cir. 2006).[4]

[4] Defendants argue that we should review the district court's implicit determination that Zhou had forfeited her scheme liability claim for an abuse of discretion. In support, they cite our decision in Curet-Velázquez v. ACEMLA de Puerto Rico, Inc., 656 F.3d 47 (1st Cir. 2011). However, that case describes our standard of review of a "district court's conclusion that a party has waived an issue by failing to adequately assert it before the magistrate judge." Id. at 54. Here, the district court decided the motion to dismiss in the first instance and never explicitly ruled that Zhou forfeited her scheme liability claim, although the court pointed out that Zhou did not raise that theory in her brief and thus left open the door for Zhou to follow up on any scheme liability claim after oral argument. Regardless, Curet-Velázquez does not provide the correct standard of review for this appeal.

Here, Zhou brought up the scheme liability claim in a "skeletal" way, at best. When defendants filed their motion to dismiss, they requested that the district court dismiss Zhou's complaint in full. They argued in their motion that Zhou had "fail[ed] to plead a claim for violations of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder." Yet, in her opposition brief, Zhou did not argue or even suggest that the district court should not dismiss all of her complaint because defendants had failed to address one of her key claims -- scheme liability. In the normal course, a court would expect such an argument to feature prominently in the opposition to a motion to dismiss. And the burden was on Zhou to set out this argument in her responsive brief. See Mancini v. City of Providence by & through Lombardi, 909 F.3d 32, 47 (1st Cir. 2018) (explaining we would not review a claim that plaintiff failed to explicitly reference or develop in summary judgment briefing); McCoy, 950 F.2d at 22 n.7 ("Courts are entitled to expect represented parties to incorporate all relevant arguments in the papers that directly address a pending motion.").

Zhou contends that her failure to make any argument about scheme liability in her response to defendants' motion to dismiss should not be fatal. According to Zhou, she clearly stated the scheme liability claim in Count III of her complaint, thus it was defendants' burden to address that claim in their motion, and she

should not be faulted for their strategic oversight in not doing so.

To understand Zhou's argument, it is helpful to review the text of Rule 10b-5. Rule 10b-5 makes it unlawful

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) 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, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.[5] Claims under Rule 10b-5(a) and (c) often overlap and are called "scheme liability" claims. See Lorenzo v. SEC, 587 U.S. 71, 79-81 (2019).

Zhou asserts that in her complaint, she alleged both a claim for material misrepresentations or omissions under Rule 10b-5(b) and a claim for scheme liability under Rule 10b-5(a) and (c). Because, as she explains, defendants' motion to dismiss was directed only at the material misrepresentations or omissions

[5] Rule 10b-5 itself does not make any conduct unlawful but rather "encompasses only conduct already prohibited by § 10(b)." Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, 552 U.S. 148, 157 (2008).

claim, the district court erred in "sua sponte" dismissing the scheme liability claim.

In contending that she did not need to brief scheme liability in her response to the motion to dismiss, Zhou relies primarily on the party presentation principle. Zhou maintains that the district court violated this principle by dismissing her entire complaint in these circumstances.

We are unpersuaded. None of the cases Zhou relies on support her position. Zhou initially cites two Supreme Court decisions, but these cases stand only for the basic rule that our adversarial system depends on the parties to advance the "facts and arguments [that] entitl[e] them to relief." Greenlaw v. United States, 554 U.S. 237, 244 (2008) (citation omitted); United States v. Sineneng-Smith, 590 U.S. 371, 375-76 (2020). Applying this rule, the Supreme Court in Sineneng-Smith held that a court of appeals abused its discretion when, "[i]nstead of adjudicating the case presented by the parties, . . . [it] named three amici and invited them to brief and argue issues framed by the panel, including a question [not raised by either party.]" 590 U.S. at 374-75. In Greenlaw, the Supreme Court relied in part on the party presentation principle to hold that a court of appeals was not warranted in extending the defendant's sentence in a case where the defendant appealed, arguing his sentence was too long, and the government had not cross-appealed. 554 U.S. at 254. Neither of

these cases suggests the district court made any error here -- it dismissed the entire complaint only after defendants requested that exact relief.

Indeed, accepting Zhou's position arguably would turn the party presentation principle on its head. In Zhou's view, the district court had the obligation, when faced with a motion to dismiss her entire complaint, to comb through all 200 pages for any plausibly alleged legal theory and assess whether defendants adequately addressed each theory regardless of whether Zhou raised it in her own responsive brief. This would be unworkable to say the least -- we require parties to make their arguments squarely and distinctly to the district court precisely because "[o]verburdened trial judges cannot be expected to be mind readers." McCoy, 950 F.2d at 22.

Zhou also points to three out-of-circuit securities fraud cases to support her position that it was defendants' burden to address any scheme liability claim in their motion to dismiss, but the facts of those cases are different in important ways. For example, the United States Court of Appeals for the Ninth Circuit recently held that Rhode Island had not waived a scheme liability claim by failing to use the specific phrase "scheme liability" or citing to Rule 10b-5(a) and (c) in its opposition to a motion to dismiss. In re Alphabet, Inc. Sec. Litig., 1 F.4th 687 (9th Cir. 2021). As the Ninth Circuit explained, "because [the] motion to

dismiss did not target Rhode Island's Rule 10b-5(a) and (c) claims, Rhode Island did not waive those claims by failing to address them" head on in its responsive brief. Id. at 709. Like here, defendants' motion to dismiss in Alphabet was directed at Rhode Island's entire complaint. Mot. to Dismiss at 18, In re Alphabet, Inc. Sec. Litig., No. 18-CV-06245 (N.D. Cal. Feb. 5, 2020), 2019 WL 4739974. But, critically, Rhode Island had argued in its opposition brief filed with the district court that defendants' motion was "limited to only one aspect of [its] allegations." Pl.'s Opp'n to Mot. to Dismiss at 7, In re Alphabet, Inc. Sec. Litig., No. 18-CV-06245 (N.D. Cal. Feb 5, 2020), 2019 WL 4739973 (cleaned up). Although Rhode Island did not reference Rule 10b-5(a) or (c) or "scheme liability" explicitly, it did refer to the paragraphs in its complaint that it later tied to its scheme liability claim in its brief to the Ninth Circuit. Id.; see also Appellant's Opening Br. at 24-31, In re Alphabet, Inc. Sec. Litig., 1 F.4th 687 (9th Cir. 2021) No. 20-15638, 2020 WL 4354497. Thus, Rhode Island did not leave the district court to "ferret out" its potential legal claims. Rivera-Gomez, 843 F.2d at 635.

The second case Zhou cites is even less on point factually. See Burt v. Maasberg, No. CIV.A. 12-0464, 2014 WL 1291834 (D. Md. Mar. 28, 2014). In Burt, the district court found that plaintiffs' claims under Rule 10b-5(b) as well as their claims under Rule 10b-5(a) and (c) survived the motion to dismiss. Id.

at *2. But there, plaintiffs had explicitly argued in their opposition brief that allegations in their complaint established separate violations of each subpart of Rule 10b-5. Pl.'s Opp'n to Mot. to Dismiss at 17-27, Burt v. Maasberg, No. CIV.A. 12-0464 (D. Md. Mar. 28, 2014), 2012 WL 8437870. In its opinion, the district court noted that the defendant had failed to offer any argument about plaintiffs' Rule 10b-5(a) and (c) claims in its reply. Burt, 2014 WL 1291834 at *24-25.

The final case Zhou relies on is also readily distinguishable. See Ansell v. Laikin, No. CV 10-9292, 2011 WL 3274019 (C.D. Cal. Aug. 1, 2011). In Ansell, the district court held that plaintiffs' Rule 10b-5(a) and (c) and Rule 10b-5(b) claims survived the motion to dismiss when plaintiffs alleged those claims in two separate counts of their complaint, and their opposition to the motion to dismiss laid out a stock manipulation scheme under Rule 10b-5(a) and (c) and a distinct false statements of material fact claim under Rule 10b-5(b). Id. at *3, 6; see also Compl. at 28-32, Ansell v. Laikin, No. CV 10-9292 (C.D. Cal. Aug. 1, 2011), 2010 WL 5069476; Opp'n to Mot. to Dismiss at 10-13, Ansell v. Laikin, No. CV 10-9292 (C.D. Cal. Aug. 1, 2011), ECF No. 42.

Unlike the plaintiffs in Alphabet, Burt, and Ansell, Zhou did not use her responsive brief to argue that the motion to dismiss failed to address all her claims or to expound on her

scheme liability claim. Thus, these cases do not support a conclusion that she preserved this claim.

In her final argument about scheme liability, Zhou contends that, even putting her responsive brief to the side, she sufficiently flagged this claim in a supplemental brief requested by the district court and during oral argument on the motion to dismiss. Again, we disagree.

As for the supplemental briefing, the district court requested that the parties address our decision in Abiomed -- a case that primarily discussed the scienter pleading requirement for Rule 10b-5(b) claims. See 778 F.3d at 231-32.[6] (Thus, the requested supplemental briefing was in no way about scheme liability.) In her supplemental brief, Zhou referenced Rule 10b-5(a) and (c) claims in one clause in one sentence, stating our decision in Abiomed "suggests that this Court should uphold Plaintiffs' Rule 10b-5(b) and Rule 10b-5(a) & (c) claims." This passing reference to subsections (a) and (c) in a brief addressing an entirely different issue does not constitute a developed argument sufficient to preserve a scheme liability claim.

[6] The plaintiffs in Abiomed also alleged a scheme liability claim involving the marketing of defendants' heart pump. See Simon v. Abiomed, Inc., 37 F.Supp.3d 499, 514-17 (D. Mass. 2014), aff'd sub nom. Abiomed, 778 F.3d 228. Because the plaintiffs' scheme liability and material misrepresentations or omissions claims turned on the same allegedly false or misleading statements, our scienter analysis focused on those statements. Abiomed, 778 F.3d at 242-45.

Finally, Zhou points to her statement at the very end of oral argument on the motion to dismiss that the complaint included a scheme liability claim, which "was not fully briefed before the Court." When the district court asked why the claim was not in the motion to dismiss briefing, Zhou explained that "it was not challenged by defendant[s] in their motion to dismiss."

Even assuming it was not too late to raise her scheme liability argument at the hearing on the motion to dismiss, this short statement did not meet Zhou's burden to "spell out" her argument for the district court. See Iverson, 452 F.3d at 102. Zhou's one-sentence assertion was at least as underdeveloped as other arguments we have concluded were not preserved. See, e.g., McCoy, 950 F.2d at 22 (plaintiffs that "failed to provide any analysis of the statutory scheme[] [or] present any legal authority directly supporting their thesis" to the district court had not preserved the argument for appellate review); Cámara de Mercadeo, Industria y Distribución de Alimentos, Inc. v. Emanuelli-Hernández, 72 F.4th 361, 364 (1st Cir. 2023) (party that argued to district court that regulations were null and void because they had not been approved by the appropriate body but failed to develop that argument with any supporting law failed to preserve that argument for appeal). For instance, Zhou did not explain why the motion to dismiss should be understood, despite its language, to be directed only at a portion of her complaint.

Nor did she attempt to develop her argument in a motion for reconsideration after the district court dismissed the complaint in its entirety.[7] Cf. Rivera-Gomez, 843 F.2d at 635-36 (argument developed in the motion for reconsideration was preserved for appeal).

Thus, we conclude that Zhou did not preserve a scheme liability claim at the district court. For that reason, we need not address any argument about whether she adequately pled such a claim.

B. Material Misrepresentations or Omissions

Next, we turn to whether the district court properly dismissed Zhou's Rule 10b-5(b) claim for failure to plead material misrepresentations or omissions. Zhou argues that she adequately alleged that several of defendants' statements and omissions about their dental products were materially false or misleading. As we explain below, we disagree.

Rule 10b-5(b) makes it unlawful to, in connection with the purchase or sale of a security, "make any untrue statement of a material fact or to omit to state a material fact necessary in

[7] Even if Zhou originally was under the impression that the district court shared her view that the motion to dismiss was limited to the material misrepresentations or omissions claim, Zhou should have understood that was not the court's view after oral argument -- when the court stated that defendants' motion "was to dismiss the entire complaint" -- or, at the very latest, when the court dismissed the complaint in full.

order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). A fact or omission is material if "a reasonable investor would have viewed it as having significantly altered the total mix of information made available." Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 33 (1st Cir. 2022) (internal quotation marks omitted) (quoting Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008)).

Importantly, section 10(b) and Rule 10b-5 only prohibit omissions that engender "half-truths." Macquarie Infrastructure v. Moab Partners, L. P., 601 U.S. 257, 263 (2024). That is because section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). An omission, even if material, is actionable only if it "renders affirmative statements made misleading." Macquarie Infrastructure, 601 U.S. at 265; In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012).

With this framework in mind, we turn to the specific allegations of materially false or misleading statements in Zhou's complaint. Although Zhou alleges that dozens of the statements made during the class period were false or misleading, we address only the statements that she focuses on in her appellate brief. Those statements fall into two categories: (1) statements that allegedly misled investors into believing that Flexcera production

complied with FDA regulations; and (2) statements that allegedly misled investors into believing that Flexcera resins could achieve specific attributes using the PCA 4000. At the end of the day, we agree with the district court that Zhou has not alleged a materially false or misleading statement in either category.

1. Statements About FDA Compliance

Zhou claims that three of defendants' statements are either false or rendered misleading by defendants' failure to disclose that EnvisionTEC produced Flexcera in facilities that were not registered with the FDA.[8] They are:

- statements on Desktop Metal's website throughout portions of the class period that Flexcera Base is "an FDA 510(k) Cleared Class 2 Medical Device" and Flexcera Smile is "an FDA Class 1 Medical Device";
- statements in Desktop Metal's quarterly report that Desktop Health products -- i.e., the company's medical and dental

[8] Although Zhou quotes only three statements in this category, she cites nearly every statement from her class period in a string cite to support the proposition that "the industry standard [for regulatory compliance], as Defendants repeatedly stated here, is nothing less than full compliance." None of the statements reference the industry standard for compliance, much less support the assertion that defendants claimed that the industry standard was 100% compliance. Absent any other explanation for why these statements are misleading, Zhou's mere citation to these statements is insufficient to put them at issue on appeal. See Zannino, 895 F.2d at 17 (describing the "settled appellate rule that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived").

products -- were subject to extensive regulations and that noncompliance "would have an adverse impact on [Desktop Metal's] business and reputation"; and

- Fulop's statement during an earnings call on August 11, 2021, that "Flexcera solutions sold out within the first four weeks of launch, and we're adding capacity to meet the robust demand."

When a plaintiff alleges multiple false or misleading statements, we perform our analysis statement by statement, considering each statement in turn. See Hill, 638 F.3d at 56; see also 15 U.S.C. § 78u-4(b)(1) (requiring a securities fraud complaint to specify each misleading statement and the reason(s) why that statement is misleading). In conducting this analysis, we evaluate "[t]he immediate context of each statement -- namely, the balance of what was said on the particular occasion, and the immediate circumstances in which the particular statement was made." Shash v. Biogen, 627 F. Supp. 3d 84, 101 (D. Mass. 2022), aff'd in part, rev'd in part and remanded, 84 F.4th 1 (1st Cir. 2023) (quoting In re Bos. Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 55 (D. Mass. 1998)).

First, we conclude that Zhou has not plausibly alleged that the statement regarding Flexcera's 510(k) clearance was either false or misleading. Zhou's complaint acknowledges that Flexcera was cleared by the FDA in May 2021, and she does not

allege that Desktop Metal published this statement before the clearance date. Accordingly, Zhou has failed to allege that the website statement is itself false. Nor has Zhou explained why Desktop Metal's failure to disclose that Flexcera was being produced in a facility not registered with the FDA rendered the website statement "so incomplete as to mislead." See In re Bos. Sci. Corp. Sec. Litig., 686 F.3d at 27 (citing Hill, 638 F.3d at 57). Zhou has not argued that noncompliance with the FDA's establishment registration requirement affected 510(k) clearance. Thus, she has not connected the dots in her complaint to explain why the omission would render defendants' accurate statement about 510(k) clearance misleading, as required by the PSLRA.[9]

Second, we agree with the district court that Desktop Metal's statement that failure to comply with regulations "would have an adverse impact on [its] business and reputation" is best understood as a "cautionary statement," which disclaims full compliance rather than promises it, as Zhou contends. See Luongo,

[9] Zhou argues in her reply brief that the specifics of FDA regulations are irrelevant to this appeal. We disagree -- Zhou necessarily made the FDA's establishment registration regulations relevant by alleging that the violation of those regulations made statements about 510(k) clearance false or misleading. Although we do not need to resolve whether defendants violated those regulations, we at least need to understand how Zhou connects the establishment registration regulations to 510(k) clearance in order to conclude that she has sufficiently alleged why the website statement was rendered misleading by an omission of noncompliance.

2023 WL 6142715, at *12. In full, Desktop Metal made the following statement:

> Compliance with regulations for medical devices and solutions is expensive and time-consuming, and failure to obtain or maintain approvals, clearances, or compliance could impact financial projections and/or subject us to penalties or liabilities.
>
> Our Desktop Health products and services, and its healthcare provider customers and distributors, are and will be subject to extensive federal, state, local and foreign regulations, including, without limitation, regulations with respect to approvals and clearances for products, design, manufacturing and testing, labeling, marketing, sales, quality control, and privacy. Unless an exemption applies, we must obtain clearance or approval from the Food and Drug Administration (or comparable foreign regulatory body) before a medical device or solution can be marketed or sold; this process involves significant time, effort and expense. The healthcare market overall is highly regulated and subject to frequent and sudden change. Our failure to secure clearances or approvals or comply with regulations could have an adverse impact on our business and reputation and subject us to lost research and development costs, withdrawal of clearance/approval, operating restrictions, liabilities, fines, penalties and/or litigation.

(Emphasis added). The initial paragraph, emphasizing the cost and time-burden of compliance, and the statement that the healthcare market is "highly regulated and subject to frequent and sudden change," clearly suggest compliance is difficult. As the United States Court of Appeals for the Second Circuit aptly held,

"acknowledgments of the complexity and numerosity of applicable regulations . . . suggest[] caution (rather than confidence) regarding the extent of [a company's] compliance." Singh v. Cigna Corp., 918 F.3d 57, 64 (2d Cir. 2019).

Zhou cites In re Gilead Sciences Securities Litigation as an example of a court finding that allegations that a regulatory compliance statement was misleading were sufficient to survive a motion to dismiss, urging us to reach the same result here. No. C 03-0100, 2009 WL 3320492 (N.D. Cal. Oct. 13, 2009). She describes Gilead Sciences as "sustaining [a] 10(b) claim where [a] company and its officers emphasized to the public that they carefully complied with federal and state regulations," when they knew they were not in compliance due to aggressive off-label marketing of pharmaceutical products.[10] This case is different, however, because Zhou has not alleged that defendants ever stated that they carefully complied with federal regulations.

[10] It is not clear that Gilead Sciences stands for this proposition. In that case, the district court found that the complaint sufficiently alleged significant off-market sales of the pharmaceutical but did not address the challenged material misrepresentations or omissions because the defendants only asked for dismissal of the 10(b) claim against "non-speaking" defendants. The district court granted the motion because there were not sufficient allegations that those defendants substantially participated in the preparation of false statements. Gilead Scis., 2009 WL 3320492 at *2-4. The case was on remand from the Ninth Circuit, which had limited its appellate review to the issue of loss causation and thus also did not address whether any statements were misleading. In re Gilead Scis. Sec. Litig., 536 F.3d 1049, 1055 (9th Cir. 2008).

Finally, we conclude that Zhou did not sufficiently allege how Fulop's statement about "adding capacity to meet the robust demand" for Flexcera was rendered misleading by failing to disclose that EnvisionTEC was producing some Flexcera at the unregistered Montreal facility. When making a voluntary disclosure, a company that reveals one fact is not required to "reveal all others that, too, would be interesting, market-wise"; instead, it is required only to reveal the facts necessary to make the existing statement not "so incomplete as to mislead." Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990). The challenged statement is not incomplete or misleading for failing to admit that some Flexcera resin was produced at a non-compliant facility, because the statement itself leaves no impression about EnvisionTEC's regulatory compliance. See In re Copley Pharm., Inc. Sec. Litig., No. CIV.A. 94-11897, 1995 WL 169215, at *2 (D. Mass. Mar. 16, 1995) (company's uncontroverted statements of fact were not actionable based on its failure to disclose alleged noncompliance with FDA regulations -- only statements of the company's belief it was in "material compliance" with regulations were actionable); cf. Serabian v. Amoskeag Bank Shares, Inc., 24 F.3d 357, 361, 364-65 (1st Cir. 1994) (reversing dismissal in part where plaintiff alleged public statements by bank claiming that its internal processes and policies for loan review were

strong when in fact there were multiple internal process failures related to its loan review).

Zhou argues that, taken together, defendants' statements created the misleading impression that Desktop Metal fully complied with all relevant regulations. But, as we previously explained, we decide section 10(b) cases on a statement-by-statement basis, considering the immediate context of each statement. And under that analysis, Zhou's complaint falls short.

To be sure, Zhou plausibly alleged corporate mismanagement and harm to defendants' customers. But "[n]ot all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud." Abiomed, 778 F.3d at 231. This is such a case -- Zhou's allegations that Desktop Metal violated certain FDA regulations do not make out a claim that Desktop Metal defrauded its investors through material misrepresentations or omissions.

2. Statements Related to the PCA 4000

Zhou next argues that defendants made misrepresentations regarding the physical qualities of Flexcera that could be achieved with the PCA 4000, EnvisionTEC's curing box. She focuses on three statements on appeal. First, on May 17, 2021, Desktop Metal published an investor presentation that described benefits of Flexcera -- including that it is "~3x More resistant to fracture"

and "~2x More resistant to water" -- on a slide that included a picture of the PCA 4000. Second, in an interview with the California Business Journal published in June 2021, Desktop Health President Jafar represented that Flexcera could be used with EnvisionTEC printers to produce eight sets of dentures in two hours. Third, throughout portions of the class period, defendants stated on the Desktop Metal website that Flexcera is "[c]ompatible and validated for use with EnvisionTEC systems."

We agree with the district court that none of these statements "suggest[] that the PCA 4000 was actually responsible for achieving or optimizing Flexcera's touted qualities." Luongo, 2023 WL 6142715, at *12. As to the first statement, Zhou has not plausibly alleged any link between the qualities of Flexcera listed on the slide and the unlabeled image of the PCA 4000 in the corner of that slide (pictured with other EnvisionTEC products). Zhou never explained why an investor would have attributed the qualities listed there to the PCA 4000. Regarding the second statement, about the speed at which EnvisionTEC printers can produce dentures made with Flexcera, there is no plausible connection to the PCA 4000, which is a curing unit, not a printer.

We also find Zhou did not plausibly allege that the third statement -- that Flexcera was compatible with EnvisionTEC systems -- was false. Zhou does not dispute that Flexcera resins were compatible with EnvisionTEC printers or EnvisionTEC curing

units besides the PCA 4000. The complaint does not allege, for example, that the EnvisionTEC branded Otoflash -- the only curing unit mentioned in defendants' manufacturing instructions for Flexcera -- was incompatible with Flexcera. Nor does the complaint allege that Desktop Metal claimed Flexcera was compatible with all its products. Thus, there is no plausible claim that the general statement that Flexcera was compatible with EnvisionTEC systems was false.

Zhou argues that the challenged statements were nevertheless "misleading for the very fact that they failed to mention the Company's undisclosed sales practice of pushing the untested PCA 4000 on customers for curing Flexcera resin." We disagree. To render a statement misleading, the omission must be within the "scope of the disclosure." Hill, 638 F.3d at 60. Zhou makes no argument that defendants' questionable sales strategy pushing the PCA 4000 was within the scope of the above statements. Nor could she make such an argument, given that none of those statements link Flexcera's qualities to the PCA 4000. In Hill, we found that a company's statement that non-reimbursement posed a risk to the company's revenue projections was not misleading for failing to disclose its allegedly risky reimbursement strategy, because that strategy was "plainly beyond the scope of the disclosure." Id. at 56, 60. Here, the undisclosed sales strategy is far less related to the challenged statements.

The only case that Zhou cites on this point does not help her. See In re Plantronics, Inc. Sec. Litig., No. 19-CV-07481, 2022 WL 3653333 (N.D. Cal. Aug. 17, 2022). In that case, the district court concluded that the plaintiff sufficiently alleged that certain statements were misleading because they "attribut[ed] positive revenue results to organic consumer demand and other factors" while omitting any mention of an unsustainable sales practice. Id. at *13; see also id. at *2 ("The undisclosed sales practice resulted in essentially borrowing sales or revenues from future quarters and was, therefore, unsustainable."). That case would be analogous only if Zhou had pointed to a statement that attributed the positive qualities of Flexcera to the use of the PCA 4000.

Zhou also cites a laundry list of statements defendants made about the qualities of Flexcera generally. Those statements refer to Flexcera's superior aesthetics, strength, and flexibility. None of those statements, however, have any connection to the PCA 4000. Thus, we agree with the district court that Zhou failed to state a securities fraud claim based on those statements because she "[did] not dispute that dentures produced with Flexcera resin were generally capable of achieving the quality specifications Defendants advertised." Luongo, 2023 WL 6142715, at *12. On appeal, Zhou takes issue with the district court's conclusion, but the only allegation that Zhou cites to contradict

this conclusion is that Flexcera cured with the PCA 4000 turned out "gummy." That is not enough to show that general statements about Flexcera's qualities were false or misleading.

Because we conclude that Zhou failed to allege that any of the challenged statements were either materially false or misleading, we do not reach the issue of scienter. And because Zhou did not state any claims under section 10(b), her derivative section 20(a) claims also fail. See Abiomed, 778 F.3d at 246.

IV. CONCLUSION

For all these reasons, we **affirm** the dismissal of Zhou's complaint.