FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

IN RE ATOSSA GENETICS INC SECURITIES LITIGATION, MIKO LEVI; BANDAR ALMOSA; GREGORY HARRISON; NICHOLAS COOK, individually and on behalf of all other persons similarly situated, *Plaintiffs-Appellants*, v. ATOSSA GENETICS, INC.; STEVEN C. QUAY, an individual; CHRISTOPHER BENJAMIN, an individual; KYLE GUSE, an individual; SHU-CHIH CHEN, an individual; JOHN BARNHART, an individual; STEPHEN J. GALLI, an individual; ALEXANDER CROSS, an individual; H. LAWRENCE REMMEL, an individual, *Defendants-Appellees.*	No. 14-35933 D.C. No. 2:13-cv-01836-RSM OPINION

Appeal from the United States District Court
for the Western District of Washington
Ricardo S. Martinez, Chief Judge, Presiding

Argued and Submitted May 18, 2017
Seattle, Washington

Filed August 18, 2017

Before: Ronald M. Gould and Richard A. Paez, Circuit Judges, and Ivan L.R. Lemelle,* District Judge.

Opinion by Judge Gould

SUMMARY**

Securities Fraud

The panel affirmed in part, reversed in part, and vacated in part the district court's dismissal of an amended securities fraud class action complaint alleging that a company and its chairman and chief executive officer made a series of public statements about the company's breast cancer screening products that were materially false or misleading.

The panel held that the plaintiffs properly alleged falsity and materiality as to some, but not all, of defendants'

* The Honorable Ivan L.R. Lemelle, Senior United States District Judge for the Eastern District of Louisiana, sitting by designation.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

statements, as required to state a claim under §§ 10(b) and 20(a) of the Securities Exchange Act and SEC Rule 10b-5.

The panel held that the plaintiffs sufficiently pled that alleged statements describing a product as cleared by the FDA were false. Plaintiffs' allegations satisfied the Private Securities Litigation Reform Act by providing the reasons why the statements were misleading. Plaintiffs also properly pled materiality because there was a substantial likelihood that the disclosure of the omitted fact would have been viewed by a reasonable investor as having significantly altered the total mix of information made available.

The panel concluded that alleged statements describing another product as FDA-cleared were neither false nor misleading in context.

The panel held that the company's Form 8-K filing with the SEC, giving notice of an FDA warning letter, was misleading, and neither the "bespeaks caution" doctrine nor the PSLRA's safe harbor, exempting defendants from liability for forward-looking statements accompanied by certain cautionary language, applied. The panel also concluded that the information omitted from the alleged filing was material.

The panel held that the plaintiffs did not sufficiently plead that an alleged statement in a quarterly report, that the company was "reasonably confident" in its responses to the FDA, was false or misleading.

Finally, the panel held that an opinion statement regarding FDA clearance risk was misleading by omission, and the omissions were material.

COUNSEL

Marc Ian Gross (argued), Jeremy Lieberman, and Michael J. Wernke, Pomerantz LLP, New York, New York; Jeffrey C. Block, Whitney E. Street, and Mark A. Delaney, Block & Leviton LLP, Boston, Massachusetts; Dan Drachler, Zwerling Schachter & Zwerling LLP, Seattle, Washington; for Plaintiffs-Appellants.

Gregory L. Watts (argued), and Barry M. Kaplan, Wilson Sonsini Goodrich & Rosati, Seattle, Washington; Cheryl W. Foung, Wilson Sonsini Goodrich & Rosati, Palo Alto, California; for Defendants-Appellees.

OPINION

GOULD, Circuit Judge:

We consider how and the extent to which our securities laws protect the investing public. Miko Levi, Bandar Almosa, Gregory Harrison, and Nicholas Cook ("Plaintiffs") appeal the district court's dismissal of their amended securities fraud class action complaint. Plaintiffs allege that Atossa Genetics, Inc. ("Atossa") and its Chairman and Chief Executive Officer, Steven Quay, made a series of public statements about Atossa's breast cancer screening products that were materially false or misleading. The district court concluded that these statements were not false or misleading, or were not material. We hold that Plaintiffs have properly alleged falsity and materiality as to some, but not all, of these statements. We affirm in part, reverse in part, vacate in part, and remand.

I

The following facts are alleged in Plaintiffs' amended complaint or are found in documents to which the allegations refer in the amended complaint. *See In re Quality Sys., Inc. Sec. Lit.*, —F.3d—, No. 15-55173, 2017 WL 3203558, at *6 (9th Cir. July 28, 2017). For purposes of this appeal, we assume that these facts are true. *See S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008).

Atossa develops and markets products used to detect pre-cancerous conditions that foreshadow the development of breast cancer. In 2009, Atossa acquired the patent rights to a product called the Mammary Aspirate Specimen Cytology Test System ("MASCT System"). The MASCT System is a pump designed to extract nipple aspirate fluid ("NAF") from women's breasts, after which the NAF can be used to detect or predict breast cancer.

Before Atossa purchased the patent rights to the MASCT system, the product had been cleared by the U.S. Food and Drug Administration ("FDA") pursuant to a procedure called "premarket notification," or the "510(k) process." This procedure allows a manufacturer to introduce a device to market that is "substantially equivalent" to a device already legally marketed in the United States, so long as the FDA provides "clearance" for the device in the form of a letter. *See generally* 21 C.F.R. §§ 807.81–807.100. The FDA cleared the MASCT System for use as a sample collection device with the provision that the NAF collected by the device could be used for the detection of cancerous and pre-cancerous cells. The FDA did not clear the MASCT System for the screening or diagnosis of breast cancer.

After first marketing the MASCT System as a standalone product, Atossa began to market it in combination with a

diagnostic tool called the ForeCYTE Test. The combined products worked in two steps. First, health care professionals would use the MASCT System to collect NAF from patients. Second, Atossa would use the ForeCYTE Test in its Seattle laboratory to inspect the NAF samples for cancer indications.[1]

But, and importantly here, Atossa never obtained FDA clearance for either the ForeCYTE Test or the combination of the MASCT System and the ForeCYTE Test.

In November of 2012, Atossa raised capital through an initial public offering ("IPO"). As part of the IPO, Atossa filed offering documents with the Securities and Exchange Commission ("SEC"), which described the MASCT System as cleared by the FDA. The documents did not state whether the ForeCYTE Test had been FDA-cleared. However, the documents said that "[t]o date, the FDA has decided, as a matter of enforcement discretion, not to exercise its authority with respect to most 'home brew' tests performed by high complexity laboratories certified under [federal standards], which is the type of laboratory that we have established." Atossa cautioned that "it [was] likely that the FDA w[ould] impose additional or new regulations affecting [laboratory-developed tests], including requiring premarket notification or approval for [such] tests." In other words, at the time of

[1] In the public statements at issue in this case, Atossa and Quay sometimes use the labels "ForeCYTE Test" and "ForeCYTE Breast Health Test" as the amended complaint does, to refer to the cancer test Atossa performed on NAF at its laboratory. But at other times, Atossa and Quay use those same labels to describe the combination of the lab test and the breast pump. At still other times, it is unclear whether Atossa and Quay are referring to both products, or to only the lab test. For clarity, we follow the lead of the amended complaint and use the name "ForeCYTE Test" to describe only the lab test.

the IPO, Atossa thought that it could market the ForeCYTE Test without seeking FDA clearance, but also thought that the FDA was likely to require such clearance in the future. The offering documents also warned that if Atossa modified a device that had already received clearance for a specific use, any modification "may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or [other] approval is obtained."

Following the IPO, Atossa and Quay made the public statements at issue in this appeal. First, on December 20, 2012, Atossa filed a Form 8–K report with the SEC, announcing Atossa's financial results for the third quarter of 2012. That filing quotes Quay as saying that "[t]he proceeds from the IPO will enable us to accelerate the national roll-out of our first FDA-cleared and marketed product, the ForeCYTE Breast Health Test for breast cancer risk assessment." In the same filing, Atossa describes itself as "focused on preventing breast cancer through the commercialization of patented, FDA-cleared diagnostic medical devices and patented, laboratory developed tests (LDT) that can detect precursors to breast cancer up to eight years before mammography."

On February 22, 2013, News-Medical.Net published an interview with Quay wherein he was asked about "the new test developed by Atossa Genetics." In his response, Quay brought up the "ForeCYTE Breast Health test," calling it "literally a Pap smear for breast cancer." The interviewer then asked Quay, "[w]hat stage of development is this test currently at?" Quay answered, "[i]t has gone through all of the FDA clearance process, which is a multi-year, multi-million dollar process."

Two days before the interview was published, on February 20, 2013, the FDA sent a warning letter to Atossa.

The letter stated that during an inspection of Atossa's laboratory, the FDA discovered that Atossa had modified the method by which the MASCT system collected NAF, without Atossa obtaining a new 510(k) clearance. According to the FDA, this meant that the MASCT System was misbranded and adulterated in violation of the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 351, 352. The FDA explicitly advised that the modified MASCT System required submission of a new 510(k) premarket notification, and that the ForeCYTE Test required independent clearance before marketing. The FDA also explicitly advised that Atossa's website and product labels were displaying false or misleading statements because they characterized the MASCT System as "FDA-approved" and the ForeCYTE Test as "FDA Cleared."

Five days later, on February 25, 2013, Atossa filed a Form 8–K report with the SEC giving notice that it had received the warning letter from the FDA. Atossa in that report explained that the FDA believed that modifications to the MASCT System required that Atossa receive a new 510(k) clearance. However, Atossa did not at all mention the FDA's concerns regarding (a) the ForeCYTE Test's lack of FDA approval, or (b) Atossa's false or misleading marketing materials. Instead, Atossa stated the following:

> The Letter also raises certain issues with respect to the Company's marketing of the [MASCT] System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. . . . Until these issues are resolved Atossa may be subject to additional regulatory action by the FDA, and any such

> actions could disrupt the Company's ongoing business and operations.

On the same day that Atossa filed the Form 8–K report giving notice of the FDA's letter, one of Atossa's IPO underwriters, Dawson James Securities, issued an analyst report maintaining a "BUY" recommendation for Atossa. The report stated that if the FDA ultimately required Atossa to file a new 510(k) notification because of its changes to the MASCT System, Atossa could still continue to market the original MASCT System. On this basis, the report concluded that "Atossa will be able to suitably reply to the FDA's concerns as expressed in the Warning Letter."

On March 15, 2013, Quay gave an interview to the Wall Street Transcript, published three days later, in which he said the following about Atossa's strategy: "I mean, 2013 and 2014 are execution years, where FDA clearance risk has been achieved, patents have been obtained, clinical trials have been achieved, manufacturing has been achieved—so now it's really a matter of going from less than 100 doctors doing our test to the expectation of thousands of doctors."

On the same day that Quay participated in that interview, Atossa responded to the FDA. Atossa told the FDA that it intended to submit a new 510(k) premarket notification for the MASCT System, and asked the FDA to post Atossa's response on the FDA's website. The FDA posted both its warning letter and Atossa's response to the letter on its website. The amended complaint does not allege a particular date on which the FDA made the warning letter public online. However, the FDA's webpage containing the letter lists March 20, 2013 as the "Page Last Updated" date. The parties agree that the FDA uploaded the letter at the latest by March 20, 2013.

On May 22, 2013, a stock market analyst issued a "BUY" recommendation for Atossa, titled "BUY Marketing blitz continues for Atossa." The recommendation was based on several factors, including Atossa's "two approved products."

Atossa submitted a new 510(k) premarket notification to the FDA, but in August of 2013 it withdrew the new notification after Atossa became aware that the FDA was unlikely to grant a clearance. Atossa did not disclose to investors that it withdrew the new notification. Meanwhile, on August 14, 2013, Atossa filed a Form 10–Q quarterly report with the SEC, which stated that Atossa was "reasonably confident in its responses" to the FDA's warning letter.

On September 19, 2013, the FDA told Atossa that it must recall both the MASCT System and the ForeCYTE Test because Atossa was marketing the products without FDA clearance. Six days later on September 25, 2013, Quay participated in a public webinar via Moneyshow.com titled "How to Invest Ahead of Breast Cancer Awareness Month." Quay did not during that webinar mention the FDA's recall demand.

On October 4, 2013, Atossa publicly disclosed that it was recalling the MASCT System and ForeCYTE Test from the market. Atossa stated:

> The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE [Test] has not been cleared or approved by the FDA for any indication. The ForeCYTE [Test] and the MASCT device are not a

> replacement for screening mammograms, diagnostic imaging tests, or biopsies.

Within three days, Atossa's share price plummeted, dropping by more than 46%. Because of the recall, all of Atossa's product and service revenue came to an abrupt end.

Plaintiff Nicholas Cook filed a putative class action against Atossa, several of its directors and officers, and three securities firms that underwrote Atossa's IPO ("Defendants"). The district court appointed Miko Levi, Bandar Almosa, and Gregory Harrison as lead plaintiffs. In the amended complaint, Plaintiffs allege violations of Sections 11 and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77o; Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a); and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5.

The district court dismissed the amended complaint without prejudice. The district court first concluded that Plaintiffs lacked statutory standing to assert their Section 11 claims. Second, the district court concluded that Plaintiffs did not plead "materiality" or "falsity" with sufficient particularity for their Section 10(b) and Rule 10b–5 claims. And finally, the district court concluded that Plaintiffs' Section 15 and Section 20(a) claims, concerning control person liability, failed because such claims require proof of a primary violation of the securities laws, which in the district court's view Plaintiffs did not properly allege. In this appeal, Plaintiffs challenge the district court's decision only as to the Section 10(b), Section 20(a), and Rule 10b–5 claims.

II

We have jurisdiction to decide this appeal under 28 U.S.C. § 1291. "We review de novo a district court's grant of a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) and for failure to allege fraud with particularity under Federal Rule of Civil Procedure 9(b)." *WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1047 (9th Cir. 2011). We "accept the [P]laintiffs' allegations as true and construe them in the light most favorable to [P]laintiffs." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 612 (9th Cir. 2017) (internal quotation marks omitted).

III

Under Section 10(b) of the Securities Exchange Act of 1934, it is unlawful "[t]o 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." 15 U.S.C. § 78j(b). Pursuant to this provision, the SEC promulgated Rule 10b–5, which makes it unlawful 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, . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5.

To state a claim for securities fraud under this rule, Plaintiffs must plead six elements: "(1) a material misrepresentation or omission by the defendant; (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." *Reese v. Malone*, 747 F.3d 557, 567 (9th Cir. 2014) (internal quotation marks omitted), *overruled on other grounds by City of Dearborn Heights*, 856 F.3d 605.

Because Plaintiffs allege violations of Section 10(b) and Rule 10b–5, their amended complaint must satisfy the dual pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"), 109 Stat. 737. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). Rule 9(b) requires that Plaintiffs "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The PSLRA requires that Plaintiffs plead with particularity both falsity and scienter. *Reese*, 747 F.3d at 568.

The district court rejected Plaintiffs' Section 10(b) and Rule 10b–5 claims on falsity and materiality grounds. In reviewing the district court's falsity rulings, we look to the PSLRA's heightened pleading standards. We ask whether Plaintiffs in the amended complaint "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). "[I]f an allegation regarding the statement or omission is made on information and belief," Plaintiffs must "state with particularity all facts on which that belief is formed." *Id.*

For Plaintiffs to satisfy materiality, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). Plaintiffs' allegations must "suffice to raise a reasonable expectation that discovery will reveal evidence satisfying the materiality requirement, and to allow

the court to draw the reasonable inference that the defendant is liable." *Reese*, 747 F.3d at 568 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011)). Where a complaint contains only "[c]onclusory allegations of law and unwarranted inferences," dismissal of the complaint on materiality grounds is appropriate. *In re VeriFone Sec. Litig.*, 11 F.3d 865, 868 (9th Cir. 1993).

Below, we address whether Plaintiffs sufficiently pled falsity and materiality for each statement at issue in this appeal.[2]

A

We begin with Quay's two alleged statements describing the ForeCYTE Test as cleared by the FDA. In the Form 8–K report filed on December 20, 2012, Quay is quoted as saying that "[t]he proceeds from the IPO will enable us to accelerate the national roll-out of our first FDA-cleared and marketed product, the ForeCYTE Breast Health Test for breast cancer risk assessment." In the interview with News-Medical.Net, Quay answered a question about the ForeCYTE test by saying "[i]t has gone through all of the FDA clearance process."

Plaintiffs have sufficiently pled that these alleged statements were false. Plaintiffs allege that Atossa did not receive FDA clearance for the ForeCYTE test or for the combination of the ForeCYTE test and the MASCT System. These allegations directly contradict Quay's alleged statements that the ForeCYTE test was FDA-cleared. The

[2] Defendants ask that we also rule on whether Plaintiffs properly pled scienter, but because the district court did not reach scienter in its order dismissing the amended complaint, we decline to address scienter in the first instance.

allegations satisfy the PSLRA by providing the "reasons why the statement[s are] misleading." 15 U.S.C. § 78u-4(b)(1).

Plaintiffs have also properly pled materiality. As alleged, the MASCT System and ForeCYTE Test were Atossa's main sources of revenue. If reasonable investors had known that the ForeCYTE Test was not FDA-cleared, and therefore was at risk of government action that could remove the product from the market, such investors doubtless would have been less keen to invest in Atossa. The stock analyst's "BUY" rating, based in part on Atossa's "two approved products," confirms that FDA clearance for the ForeCYTE Test was relevant to investing decisions. Because the ForeCYTE Test was allegedly central to Atossa's business strategy, the knowledge that the test was not FDA-cleared would have, for a reasonable investor, "significantly altered the 'total mix' of information made available." *Basic*, 485 U.S. at 232 (internal quotation marks omitted).

There is also little reason to think that the market was aware that Quay's alleged statements were false. Atossa's alleged IPO documents did not contradict Quay's assertions. The alleged documents stated that the MASCT System was FDA-cleared, but were silent regarding clearance for the ForeCYTE Test. Defendants point to Atossa's cautionary language stating that the FDA likely would require premarket notification for certain lab tests in the future. Defendants contend that this warning implied that the ForeCYTE Test was not FDA-cleared. But we reject this dubious proposition. That the FDA did not require clearance at the time of the IPO, does not indicate that the ForeCYTE test was not cleared. Atossa's warning also shows why Quay's alleged false statements were consequential: If the

FDA was likely to start requiring clearance, then surely a reasonable investor would care whether Atossa's test was FDA-cleared.

This conclusion is reinforced by our view of the doctrine of reliance and its relationship to materiality. As earlier mentioned, one of the elements Plaintiffs must allege to state a claim for securities fraud is reliance on the false or misleading statement. Plaintiffs can satisfy this element in several ways. Most directly, Plaintiffs can allege that they were aware of, and specifically relied on, Quay's false statements when deciding to purchase or sell Atossa shares. *See, e.g.*, *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1159 (9th Cir. 1996). Under this theory of reliance, it does not matter whether Atossa's alleged offering documents previously revealed that the ForeCYTE Test was not cleared. If Quay's alleged statements contained false information about a subject that reasonable investors would consider important, and Plaintiffs relied on those statements, then those statements are material. *See In re Apple Comput. Sec. Lit.*, 886 F.2d 1109, 1114 (9th Cir. 1989) ("Ordinarily, omissions by corporate insiders are not rendered immaterial by the fact that the omitted facts are otherwise available to the public."); *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 887 (9th Cir. 2008) ("[I]nvestors are not generally required to look beyond a given document to discover what is true and what is not.").

Certainly the calculus for materiality would change where Plaintiffs allege reliance less directly, for example solely through a "fraud on the market" theory. Under a fraud on the market theory, Plaintiffs would not allege that they directly relied on Quay's particular false statement, but rather that they relied on the integrity of the market price for Atossa shares, which itself reflected all market data. *See*

Apple Computer, 886 F.2d at 1114 ("In a fraud on the market case, the plaintiff claims that he was induced to trade stock not by any particular representations made by corporate insiders, but by the artificial stock price set by the market in light of statements made by the insiders as well as all other material public information."). Unlike direct reliance, under a fraud on the market theory, it is possible for true information to enter the market and nullify the effect of the false statement on the stock price, thereby making the false statements immaterial.

But here, Plaintiffs pled both that they relied directly on the statements by Quay and Atossa, as well as the integrity of Atossa's stock price. So even if the alleged IPO documents were assumed to have conveyed the truth about clearance for the ForeCYTE Test (which we conclude they did not), and even if such truthful information canceled out the effect of Quay's alleged false statements on Atossa's stock price, Quay's alleged statements would still be material under a theory of direct reliance, which Plaintiffs here adequately pled.

We hold that Plaintiffs have properly pled falsity and materiality for Quay's statements that the ForeCYTE Test was FDA-cleared.

B

We next address Atossa's alleged statements describing the MASCT System as FDA-cleared. The FDA allegedly cleared the MASCT System only for use in collecting NAF samples. The IPO documents stated this explicitly in some places. They explained, for instance, that the MASCT System had been cleared "for the collection of NAF" with the provision that "the NAF collected using the MASCT System can be used in the determination and/or

differentiation of normal versus premalignant versus malignant cells."

But in a different place in the offering documents, as well in the Form 8–K filing of December 20, 2012, Atossa used less precise language. Atossa stated only that the MASCT System was FDA-cleared, without specifying the purpose for which it had been cleared. These alleged statements are: (1) the IPO documents' mention of "FDA-cleared *Mammary Aspirate Specimen Cytology Test*, or MASCT, System (our MASCT System received 510(k) clearance from the FDA in 2003)"; and (2) the Form 8–K reference to the MASCT System as "patented, FDA-cleared diagnostic medical devices."

These alleged statements were not false. The MASCT System had received 510(k) clearance, and the statements portrayed the MASCT System as having received that clearance. Nevertheless, Plaintiffs contend that while true, the alleged statements were misleading in context. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) ("[A] statement that is literally true can be misleading and thus actionable under the securities laws."). Plaintiffs assert that Atossa "portrayed the 'cleared' MASCT system as part of its breast cancer screening system," even though it had only been cleared for sample collection, not screening. Plaintiffs contend that based on Atossa's statements, a reasonable investor would have believed that the MASCT System was FDA-cleared for the purpose for which Atossa was marketing the product—the detection of breast cancer and the precursors to breast cancer.

But Plaintiffs' theory in this respect must be rejected. As allegedly marketed by Atossa, the MASCT System performed only a collection role. It was used to collect the NAF, which was sent to Atossa's lab where the ForeCYTE

Test screened the NAF for cancerous and precancerous cells. The result was a cancer screen, but the MASCT System's alleged role in the process was precisely that for which it allegedly had been cleared—collection. Nowhere do Plaintiffs allege that the MASCT System itself screened for cancer. Plaintiffs' amended complaint therefore does not specify "the reason or reasons why the statement[s are] misleading." 15 U.S.C. § 78u-4(b)(1); *see Brody*, 280 F.3d at 1006 (defining misleading as "affirmatively creat[ing] an impression of a state of affairs that differs in a material way from the one that actually exists."). We conclude that Atossa's alleged general statements that the MASCT System was FDA-cleared were not misleading.

To be sure, as alleged, the FDA eventually demanded a recall of the MASCT System, even despite the FDA's previous grant of 510(k) clearance for the product. But the alleged reason for the recall was not that Atossa used the MASCT System for a non-cleared purpose. Rather, Atossa allegedly had changed the MASCT System's collection method without filing a new 510(k) notification. Plaintiffs do not contend that Atossa's statements were misleading because the MASCT System was modified; they contend only that Atossa marketed the MASCT System for a non-cleared purpose.

We hold that Plaintiffs have not sufficiently alleged that Atossa's statements concerning FDA clearance for the MASCT System were false or misleading, and we affirm in part as to that conclusion.[3]

[3] We need not, and do not, reach whether Plaintiffs properly pled that those statements were material.

C

We next address whether Atossa's Form 8–K filing on February 25, 2013, giving notice of the FDA's warning letter, was materially false or misleading. The filing explained the FDA's concerns regarding modifications to the MASCT System, but left out the FDA's alleged concerns about (a) the ForeCYTE Test lacking clearance, and (b) Atossa's false and misleading marketing materials. Instead, Atossa stated the following:

> The Letter also raises certain issues with respect to the Company's marketing of the [MASCT] System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. . . . Until these issues are resolved Atossa may be subject to additional regulatory action by the FDA, and any such actions could disrupt the Company's ongoing business and operations.

Atossa's above-quoted language omitted the balance of the FDA's alleged serious concerns. We conclude that, though not literally false, the alleged omissions in the Form 8–K filing were misleading. In particular, the omissions gave the reasonable inference that the FDA had raised no concerns related to clearance for the ForeCYTE Test, when, as alleged, the FDA had raised precisely that concern. The amended complaint's allegations suggest that, regrettably for the investors who bought Attosa's stock, Atossa hid the ball. *See, e.g.*, *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) ("[T]he concerns raised by the FDA . . . were much more significant than a 'bump on the road' and

shed serious doubt on the sufficiency of the trials. Accordingly, Defendants were obligated to disclose the FDA's concerns to render their statement not misleading.").

Atossa's general disclaimer that it could be subject to future regulatory action from "other matters" does not cure the misleading nature of its alleged filing. We measure the protective function of forward-looking cautionary language using the "bespeaks caution" doctrine. *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1413 (9th Cir. 1994). The doctrine "provides a mechanism by which a court can rule as a matter of law . . . that defendants' forward-looking representations contained enough cautionary language or risk disclosure to protect the defendant against claims of securities fraud." *Id.* (internal quotation marks omitted). But "[d]ismissal on the pleadings under the bespeaks caution doctrine . . . requires a stringent showing: There must be sufficient cautionary language or risk disclosure such that reasonable minds could not disagree that the challenged statements were not misleading." *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 947 (9th Cir. 2005) (alteration and internal quotation marks omitted). To meet this standard, "the language bespeaking caution [must] relate directly to that to which plaintiffs claim to have been misled." *Worlds of Wonder*, 35 F.3d at 1415 (quoting *Kline v. First W. Gov't Sec., Inc.*, 24 F.3d 480, 489 (3d Cir. 1994)).

Here, Atossa referred to the FDA's ForeCYTE Test concerns using the broad phrase "among other matters," and closed with the similarly broad warning, "[u]ntil these issues are resolved Atossa may be subject to additional regulatory action by the FDA." This language is not "directly" related to FDA clearance for the ForeCYTE Test, is vague enough to cover any concern the FDA might have had related to Atossa, and obscures the issue of concern to reasonable

investors whether the ForeCYTE Test was FDA-cleared. *See Worlds of Wonder*, 35 F.3d at 1415. We conclude that reasonable minds could disagree that Atossa's alleged language was not misleading. The bespeaks caution doctrine does not protect Defendants from liability.

> Nor does the PSLRA's safe harbor, which is a "statutory version" of the bespeaks caution doctrine. *Emp'rs Teamsters Local Nos. 175 & 505 Pension Tr. Fund v. Clorox Co.*, 353 F.3d 1125, 1132 (9th Cir. 2004). The PSLRA's safe harbor provision exempts from liability forward-looking statements accompanied by certain cautionary language. *See* 15 U.S.C. § 77z–2; *Quality Systems*, 2017 WL 3203558, at *7. But the misleading part of Atossa's Form 8–K filing—how it characterized the FDA's warning letter—concerned only past facts, not statements about the future. The filing therefore falls outside of the PSLRA's safe harbor.

We conclude that Plaintiffs have sufficiently alleged that Atossa's Form 8–K filing giving notice of the FDA's warning letter was misleading. Perhaps most importantly, the alleged warning letter had expressly said that the ForeCYTE Test was not FDA-cleared, but the alleged responsive filing from Atossa studiously avoided disclosing that fact.

We also conclude that the information omitted from the alleged filing was material. Just as a reasonable investor would find it relevant that the ForeCYTE Test was not FDA-cleared, such an investor would find it relevant that the FDA raised concerns about the ForeCYTE Test not being cleared.

Indeed, in the latter case, the prospect of Atossa being forced by the FDA to pull the ForeCYTE Test from the market is an even more likely possibility.

Atossa contends that its characterization of the alleged warning letter was immaterial because the warning letter was publicly available. But this argument suffers from two flaws. First, public disclosure of the alleged letter is relevant to materiality only to the degree that Plaintiffs rely on a fraud on the market theory of reliance. *See Apple Comput.*, 886 F.2d at 1114. As explained earlier, Plaintiffs allege both direct reliance on Atossa's statements and reliance on the integrity of the market price. Under Plaintiffs' direct reliance theory, disclosure of the alleged letter is irrelevant to materiality. *See Miller*, 519 F.3d at 887.

Second, for purposes of this appeal, we presume that the FDA warning letter was not publicly available at the time Atossa filed its misleading Form 8–K report. Plaintiffs were the nonmoving party in the district court, so we must construe all factual allegations in their favor. *See Outdoor Media Grp., Inc. v. City of Beaumont*, 506 F.3d 895, 900 (9th Cir. 2007). The amended complaint and the documents mentioned in it do not list the date on which the letter was made public. But the alleged printout of the warning letter from the FDA's website lists March 20, 2013 as the "Page Last Updated" date. At this stage, we must grant Plaintiffs the reasonable inference that the "Page Last Updated" date is the same date on which the FDA initially uploaded the warning letter. March 20, 2013 is nearly a month after Atossa filed its Form 8–K report addressing the letter, too

late for the letter's public disclosure to affect the materiality of omissions from the filing.[4]

Finally, Plaintiffs have moved for us to take judicial notice of Atossa's stock price from March 14, 2013 to March 26, 2013, which sharply increased. Plaintiffs contend that the increase in Atossa's stock price during that thirteen-day period shows that even if the FDA letter became public on March 20, 2013, the information in the letter did not at that time "enter the market" by becoming known to market observers. We GRANT the motion for judicial notice because historical stock prices are "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). However, Atossa's stock price during that period does not affect our analysis one way or the other. The price increase from March 14, 2013 to March 26, 2013 might reflect that the letter did not quickly enter the market when made public on March 20, 2013. But it might also reflect that the letter was in fact made public long before March 20, 2013, and any price decrease it caused predated Plaintiffs' chosen thirteen-day period. Without a record of price stretching back to an earlier point, we decline to give weight to Atossa's stock price in our analysis of whether Atossa's alleged Form 8–K filing was misleading.

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[4] The analyst report from Dawson James Securities lends support to the factual inference that the warning letter was not publicly available at the time of Atossa's Form 8–K filing. As alleged, the analyst report mentioned the FDA's concerns about modification to the MASCT System, but did not mention any concerns about the ForeCYTE Test lacking FDA clearance. If the letter had been publicly available, one would expect a securities firm that analyzed Atossa, and had been involved in Atossa's IPO, to be aware of the letter's contents.

For the other reasons stated above, we infer at this stage that the warning letter was not publicly available at the time of Atossa's alleged Form 8–K filing giving notice of the letter. We hold that Plaintiffs have properly pled that the filing was materially misleading.

D

We next address the statement in Atossa's Form 10–Q quarterly report that Atossa was "reasonably confident in its responses" to the FDA's warning letter.

Plaintiffs first contend that this alleged statement was false or misleading because at the time of the filing, Atossa had already submitted and withdrawn a new 510(k) notification for the MASCT System. In the Plaintiffs' view, a feeling of reasonable confidence was inconsistent with Atossa withdrawing the notification.

We disagree. "When valuing corporations, [] investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010). Such corporate "puffing" is not actionable as misleading under the securities law. *See id.* ("[A] mildly optimistic, subjective assessment hardly amounts to a securities violation. Indeed, professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives." (internal quotation marks omitted)). Atossa's alleged statement that it was "reasonably confident" in its responses to the FDA's letter is unspecific, subjective, and only guardedly optimistic. "In context, any reasonable investor would have understood [Atossa's alleged] statement[] as mere corporate optimism." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014); *see id.* at 1060–61 (concluding that statements that company

is "reservedly optimistic" about sales and "in a pretty good position" despite the economic crisis are "the antithesis of facts" and "represent the feel good speak that characterizes non-actionable puffing" (internal quotation marks omitted)). We conclude that Plaintiffs have not sufficiently alleged that Atossa's guarded statement that it was "reasonably confident" in its responses to the FDA was false or misleading.

Plaintiffs also contend that Atossa's Form 10–Q report was misleading by omission. Plaintiffs assert that by commenting on the prospects for its responses to the FDA, without also disclosing the newly filed and withdrawn 510(k) notification, Atossa materially misled reasonable investors. But Atossa was not obligated to disclose each and every step it took when interacting with regulators. *See Matrixx Initiatives*, 563 U.S. at 44 ("[Section] 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." (alteration and internal quotation marks omitted)); *Cutera*, 610 F.3d at 1109 ("Often, a statement will not mislead even if it is incomplete or does not include all relevant facts." (internal quotation marks omitted)). Plaintiffs do not point to any particular statement in the Form 10–Q report (other than the statement of reasonable confidence, addressed above) that would be misleading in light of the withdrawn 510(k) notification. Plaintiffs have not pled "the reason or reasons why" any particular statement is misleading, as required under the PSLRA. 15 U.S.C. § 78u-4(b)(1).

We conclude that Plaintiffs have not sufficiently pled that Atossa's Form 10–Q filing was misleading, and we

affirm in part as to the district's court's rejection of this contention.[5]

E

Finally, we address the following statement made by Quay during his March 15, 2013 interview with the Wall Street Transcript: "I mean, 2013 and 2014 are execution years, where FDA clearance risk has been achieved, patents have been obtained, clinical trials have been achieved, manufacturing has been achieved—so now it's really a matter of going from less than 100 doctors doing our test to the expectation of thousands of doctors." Plaintiffs contend that Quay's suggestion that FDA clearance risk had been achieved was materially false or misleading because the FDA had not given clearance for the ForeCYTE Test. Defendants respond that the alleged statement was not false or misleading because it was forward-looking. In their view, Quay's answer conveyed that 2013 and 2014 were years when Atossa would achieve full FDA clearance.

The most natural reading of Quay's interview response is that he spoke of events that had already happened, *i.e.*, that FDA clearance risk had already been achieved. In Quay's answer, he surrounded the phrase "FDA clearance risk" with use of the past tense: "achieved"; "obtained"; "achieved"; and "achieved." This emphasis on the past tense indicates that Quay was referring to prior events.

We also reject Defendants' contention that because in an earlier question the interviewer asked Quay to summarize his priorities for the remainder of 2013, Quay's response

[5] We need not, and do not, reach whether Plaintiffs properly pled that any omission from the filing was material.

regarding FDA clearance risk must have been forward-looking. The interviewer asked the question about Quay's 2013 priorities three questions before Quay gave the response at issue, and nothing in the interview indicates that Quay's response was an answer to the earlier question.

Nevertheless, even read as a statement that Atossa had already achieved FDA clearance risk, Quay's alleged response is not plainly false. There is a difference between saying that the ForeCYTE Test was FDA-cleared, a statement of fact, and that FDA clearance risk has been achieved, which sounds more like a statement of opinion. The former is an easily verifiable past event—either the FDA has granted clearance or it has not. The latter is less black and white. What does it mean to say a risk has been "achieved"? Such a statement could convey that the risk has been reduced to zero. But it could also convey that the risk has been reduced to an acceptable level, which could mean that some degree of risk remains. Whether a risk has been "achieved" is in our view not a question of fact, but a question of opinion. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1325 (2015) ("A fact is 'a thing done or existing' or '[a]n actual happening.' An opinion is 'a belief[,] a view,' or a 'sentiment which the mind forms of persons or things.'" (quoting Webster's New International Dictionary 782, 1509 (1927)). Indeed, it is the speaker's personal definition of "achieved" that here produces the opinion. Still, we do not go as far as to classify Quay's alleged response as corporate puffery. "FDA clearance risk has been achieved" is too precise to be considered the sort of vague, optimistic language of puffery that investors know to disregard or to take with a grain of salt. *See Intuitive Surgical*, 759 F.3d at 1060. Instead, we consider Quay's alleged response to be a statement of opinion, and we analyze it as such.

We recently addressed the standards applicable to pleading falsity of an opinion statement under Section 10(b) and Rule 10b–5. *See City of Dearborn Heights*, 856 F.3d 605. We there held that the standards for evaluating such claims are the same standards the Supreme Court applied to pleading Section 11 opinion claims in its decision in *Omnicare*. We explained:

> *Omnicare* establishes three different standards for pleading falsity of opinion statements. First, when a plaintiff relies on a theory of material misrepresentation, the plaintiff must allege both that "the speaker did not hold the belief she professed" and that the belief is objectively untrue. Second, when a plaintiff relies on a theory that a statement of fact contained within an opinion statement is materially misleading, the plaintiff must allege that "the supporting fact [the speaker] supplied [is] untrue." Third, when a plaintiff relies on a theory of omission, the plaintiff must allege "facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context."

City of Dearborn Heights, 856 F.3d at 615–16 (quoting *Omnicare*, 135 S. Ct. at 1327, 1332). Plaintiffs' allegations fall into the third category. Plaintiffs allege that Quay's response minimizing FDA clearance risk was materially misleading because it omitted (a) that the ForeCYTE Test was not FDA-cleared, and (b) that the FDA had recently warned Atossa regarding its lack of clearance.

We emphasized in *City of Dearborn Heights* that "a reasonable investor expects not just that the issuer believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at the time." *Id.* at 615 (internal quotation marks omitted). Based on this, we explained that for an opinion to be misleading by omission, (1) the "statement [must] omit[] material facts about the [defendant's] inquiry into or knowledge concerning a statement of opinion," and (2) "those facts [must] conflict with what a reasonable investor would take from the statement itself." *Id.* (internal quotation marks omitted).

Here, the ForeCYTE Test's lack of 510(k) clearance, and the FDA's concerns about that lack of clearance, relate directly to the basis for Quay's opinion that FDA clearance risk had been achieved. These omitted facts concern Quay's "knowledge concerning [his] statement of opinion." *Id.* And they conflict with what a reasonable investor would take away from the statement, "FDA clearance risk has been achieved." *See Quality Systems*, 2017 WL 3203558, at *9 ("[R]eassuring investors that 'everything [was] going fine' with FDA approval when the company knew FDA approval would never come was materially misleading." (discussing and quoting *Warshaw v. Xoma Corp.*, 74 F.3d 955, 959 (9th Cir. 1996)). Moreover, the omitted facts are strikingly similar to a hypothetical the Supreme Court offered in *Omnicare*. The Supreme Court explained in *Omnicare* that if an issuer publicly stated, "[w]e believe our conduct is lawful," but did not disclose the issuer's knowledge that the Federal Government took the opposite view, reasonable investors would be misled because the issuer's opinion would not "fairly align[] with the information in the issuer's possession at the time." 135 S. Ct. at 1328–29. Here, saying that FDA clearance risk has been achieved is another way of

expressing a belief that Atossa's conduct mostly complies with FDA rules governing 510(k) clearance. And failing to disclose that the FDA gave a warning about the ForeCYTE Test not having 510(k) clearance is an omission concerning knowledge that the Federal Government has taken the opposite view concerning the lawfulness of Atossa's alleged conduct. As in the Supreme Court's hypothetical, Quay's opinion statement did not "fairly align[] with the information in [Quay's] possession at the time." *Id.* at 1329. We conclude that Quay's opinion statement that FDA clearance risk has been achieved is misleading by omission.

We also conclude that Quay's omissions are material. A reasonable investor would place great value in knowledge that one of Atossa's marquee products was not cleared by the FDA and that the FDA had expressed concern about that lack of clearance. And, as earlier discussed, by construing the allegations in Plaintiffs' favor, we infer that the FDA warning letter was not made public until March 20, 2013. This was five days after Quay made the statement regarding FDA clearance risk during his interview with the Wall Street Transcript, and two days after that interview was allegedly published. The FDA warning letter would not have had the opportunity to cure Quay's omissions. And even if the FDA's letter had been publicly available at the time of the statement, the letter could not have cured the alleged omissions under Plaintiffs' direct-reliance theory of relief. *See Miller*, 519 F.3d at 887.

We hold that Plaintiffs have properly pled falsity and materiality as to Quay's opinion statement that "FDA clearance risk has been achieved."

IV

We hold that Plaintiffs have sufficiently alleged that the following were materially false or misleading: (1) Quay's statement quoted in Atossa's December 20, 2012 Form 8–K filing describing the ForeCYTE Test as "FDA-cleared"; (2) Quay's statement during his interview with News-Medical.Net that the ForeCYTE test had "gone through all of the FDA clearance process"; (3) Atossa's Form 8–K filing on February 25, 2013, giving notice of the FDA's warning letter; and (4) Quay's statement during his interview with the Wall Street Transcript that "FDA clearance risk has been achieved." As to these alleged misstatements and omissions, we reverse in part the district court's dismissal of Plaintiffs' Section 10(b) and Rule 10b–5 claims. As to all other alleged misstatements and omissions, we affirm in part the district court's dismissal of Plaintiffs' Section 10(b) and Rule 10b–5 claims. Because the district court's dismissal of Plaintiffs' Section 20(a) claims was based on its dismissal of Plaintiffs' Section 10(b) and Rule 10b–5 claims, we vacate the district court's dismissal of the Section 20(a) claims. We remand to the district court for further proceedings consistent with this opinion.

The parties shall bear their own costs on appeal.

AFFIRMED in part, REVERSED in part, VACATED in part, and REMANDED.