United States Court of Appeals
For the First Circuit

No. 14-1502

FIRE AND POLICE PENSION ASSOCIATION OF COLORADO;
CITY OF AUSTIN POLICE RETIREMENT SYSTEM,

Plaintiffs, Appellants,

and

KARSE SIMON, individually and on behalf of all others similarly situated; ARLENE SIMON, individually and on behalf of all others similarly situated; OKLAHOMA POLICE PENSION AND RETIREMENT SYSTEM; CITY OF HOLLYWOOD (FL) EMPLOYEES' RETIREMENT FUND; TULARE COUNTY EMPLOYEES' RETIREMENT ASSOCIATION; ORLANDO POLICE PENSION FUND,

Plaintiffs,

v.

ABIOMED, INC.; MICHAEL R. MINOGUE; ROBERT L. BOWEN,

Defendants, Appellees.

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

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before
Lynch, Chief Judge,
Souter,[*] Associate Justice,
and Selya, Circuit Judge.

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

Patrick T. Egan, with whom Kristin J. Moody, Daryl DeValerio Andrews, Berman DeValerio, Robert D. Klausner, and Klausner, Kaufman, Jensen & Levinson were on brief, for appellants.

John D. Donovan, Jr., with whom Daniel V. Ward, Matthew Mazzotta, Elizabeth D. Johnston, Dara A. Reppucci, and Ropes & Gray LLP were on brief, for appellees.

February 6, 2015

LYNCH, Chief Judge. Not all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud. This case is an example.

Institutional investors, asserting claims on behalf of a putative class of purchasers of the stock of defendant Abiomed, Inc.,[1] brought suit against Abiomed and two of its officers, Michael Minogue and Robert Bowen, alleging that all defendants committed securities fraud in violation of section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5; and that the individual defendants violated section 20(a) of the Act, 15 U.S.C. § 78t(a). The alleged misleading statements and omissions concerned Abiomed's flagship product, a micro heart pump called the Impella Recover LP 2.5. The complaint alleges that defendants told investors that its policy was to avoid off-label marketing of the Impella 2.5, when in fact defendants "were orchestrating and engaged in widespread off-label market promotion." And when the Food and Drug Administration (FDA) initiated inquiries into the company's marketing tactics, defendants told investors that it was "cooperating" with the agency and "working to resolve [a] few discrete issues," when in fact the

[1] The named plaintiffs are Fire and Police Pension Association of Colorado, City of Austin Police Retirement System, Oklahoma Police Pension and Retirement System, City of Hollywood (FL) Employees' Retirement Fund, Tulare County Employees' Retirement Association, Orlando Police Pension Fund, and individual investors Karse and Arlene Simon.

company was "trivializing the concerns" and "continuing to off-label market."

The district court dismissed the complaint on the ground that plaintiffs had not pleaded facts giving rise to a "'cogent and compelling'" inference of scienter, as is required under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109. Stat. 737. Simon v. Abiomed, Inc., No. 12-12137-FDS, 2014 WL 1413638 (D. Mass. Apr. 10, 2014) (citation omitted).

We affirm. The district court correctly held that the pleadings are insufficient to establish the requisite inference of scienter. Even assuming that plaintiffs plausibly alleged that defendants made false or misleading statements which had a material effect on Abiomed's stock price -- a matter that is far from clear -- plaintiffs have not sufficiently alleged that defendants made those statements with the "conscious intent to defraud or 'a high degree of recklessness.'" ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)).

I. Factual Background

We draw the following statement of facts from plaintiffs' Amended Class Action Complaint and from materials defendants filed in the district court in support of their motion to dismiss.[2]

[2] These materials consist of correspondence between the FDA and Abiomed and public records, such as Abiomed's filings with the SEC. Neither party disputes that the court may properly consider

A. The Parties

Defendant Abiomed is a Massachusetts-based company employing approximately 150 people which develops, manufactures, markets and sells medical devices designed for circulatory support. Minogue is Abiomed's CEO, and Bowen is its CFO. Plaintiffs are a class of entities and individuals who purchased Abiomed stock from August 4, 2011, to October 31, 2012 (the "Class Period").

The allegations in the complaint are based in part on interviews with confidential witnesses who are former employees of Abiomed. Confidential Witness 1 ("CW1") "worked in a clincial/surgical support position as a clinical representative from March 2011 until April 2012." According to CW1, Abiomed employees were in close proximity to one another, and Minogue and Bowen were very "hands-on" leaders.

The Impella 2.5, "a percutaneous micro heart pump with an integrated motor and sensors" that "can pump up to 2.5 liters of blood per minute," is Abiomed's most important product. In fiscal year (FY) 2012, 85% of Abiomed's revenues came from sales of Impella products, and "most" of that revenue came from the sales of the Impella 2.5. The Impella 2.5's main competitor is the

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these materials. See Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993) (noting that, in ruling on a motion to dismiss, court may consider "documents the authenticity of which are not disputed by the parties; [] official public records; [] documents central to plaintiffs' claim; or [] documents sufficiently referred to in the complaint").

intra-aortic balloon pump (IABP), which is much cheaper and more widely used than the Impella 2.5.

B. The FDA's Regulation of Medical Devices

The FDA regulates the labeling and marketing of medical devices pursuant to the Food, Drug, and Cosmetics Act (FDCA). Under section 510(k) of the FDCA, the agency can "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. The FDA may also grant an investigational device exemption ("IDE") to a company to allow it to use a device in a clinical study to test its safety and efficacy.

Under FDA regulations, a company is not allowed to market a device for a use for which it has not been approved -- that is, an "off-label" use. However, the FDA does not prohibit physicians and hospitals from off-label use of medical devices, and a medical device company is allowed to respond to unsolicited requests from physicians for information regarding off-label uses of the company's products. FDA regulations also prohibit a company with an IDE from representing that the device is safe and effective for the purpose for which it is being tested.

C. The Protect II and Recover II Studies

In August 2007, Abiomed received an IDE from the FDA that allowed it to begin a clinical trial comparing the performance of

the Impella 2.5 to that of the IABP during high-risk percutaneous coronary interventions ("PCIs"), commonly known as angioplasties (the "Protect II Study"). The study's purpose was to measure major adverse events suffered by patients 30 days after the PCI procedure.

On December 6, 2010, Abiomed terminated the Protect II Study after finding that the Impella 2.5 did not achieve superior outcomes compared with the IABP at the 30-day endpoint. However, Abiomed continued to collect and analyze data from the study, and the study eventually yielded "exploratory" results "suggesting a possible benefit for the device at 90 days." The study was published in September 2012 in Circulation, a peer-reviewed medical journal.

In March 2008, Abiomed received an IDE for a second study (the "Recover II Study") designed to compare the Impella 2.5 to the IABP in hemodynamically unstable patients undergoing a PCI due to an acute myocardial infarction ("AMI"), more commonly known as a heart attack. The Recover II Study was suspended in September 2009 and eventually terminated due to insufficient enrollment.

D. 510(k) Clearance for the Impella 2.5, the Alleged "Pervasive" Scheme of Off-Label Marketing, and the FDA's Response

In June 2008, pursuant to the 510(k) process, Abiomed received clearance from the FDA to market and commercially distribute the Impella 2.5 for partial circulatory support for up

to six hours. Under FDA regulations, to repeat, Abiomed was not permitted to market or promote the Impella 2.5 for any other use. Plaintiffs allege that defendants flouted these regulations and "engage[d] in widespread improper promotion and marketing of the Impella 2.5." They make the following specific allegations in support of that claim.

1. The January 2010 Untitled Letter

On January 28, 2010, the FDA sent Abiomed an Untitled Letter objecting to certain of Abiomed's activities promoting the Impella 2.5. Untitled Letters are intended to address alleged regulatory violations that do not meet the threshold for regulatory significance warranting a Warning Letter. They "do[] not include a warning that a company's failure to take prompt corrective steps could lead to an enforcement action." Simon, 2014 WL 1413638, at *3 n.2 (citing U.S. Food & Drug Admin., Regulatory Procedures Manual: Advisory Actions, 2004 WL 3363386, at *24 (2010)).

The FDA stated that Abiomed had improperly "promot[ed] the Impella 2.5 for high risk PCI and AMI" and represented that the Impella 2.5 was superior to the IABP in those uses. Essentially, in the FDA's view, Abiomed's promotional materials represented that the device was effective for uses for which it was being tested under the Protect II and Recover II IDEs, which constituted a violation of FDA regulations.

Abiomed responded to the FDA letter on March 4, 2010, stating that it "now recognize[d]" that the challenged promotions had made improper efficacy claims and that it would revise its marketing materials in order to remove the offending statements. Abiomed also represented that it had "strengthened its review process" for promotional materials.

The FDA viewed this response as inadequate, however, and Abiomed made further changes to its advertisements and reviewed its marketing materials and website to ensure that "there were no other materials" beyond those identified by the FDA that made improper safety or efficacy claims. On April 20, 2010, the FDA wrote Abiomed stating that its "response appear[ed] adequate" and that no further action was necessary. Abiomed did not publicly disclose this correspondence with the FDA at that time.

2. The June 2011 Warning Letter

Over a year later, on June 10, 2011, the FDA issued an official Warning Letter to Abiomed stating that the company's "marketing materials continued to improperly compare the Impella 2.5 to the IABP and promote the device for non-cleared uses." A Warning Letter is a step above an Untitled Letter in the FDA's enforcement hierarchy. It communicates that the FDA believes the regulated entity has committed a violation of regulatory significance but does not commit the FDA to taking enforcement action. Simon, 2014 WL 1413638, at *3 n.2 (citing U.S. Food & Drug

Admin., Regulatory Procedures Manual: Advisory Actions, 2004 WL 3363386, at *1-2 (2010)).

The Warning Letter criticized an Abiomed magazine advertisement that pictured a hand puncturing a red balloon and suggested that the Impella 2.5 was superior to the IABP "for circulatory support in the Cath lab." The FDA's letter also complained about the Abiomed slogan, "Recovering Hearts, Saving Lives," which the FDA stated would require a study under an IDE "to evaluate whether the device could salvage heart tissue and muscle."[3] Finally, the agency took issue with a claim at a conference of cardiovascular physicians that the Impella could improve hemodynamics and cardiac output in AMI Shock patients, since those indications also needed to be supported with a study performed under an IDE.

The Warning Letter was posted on the FDA's website. An Abiomed spokeswoman stated publicly that the "letter addresses specific promotional items from 2010. . . . We are working with the FDA to ensure all of our promotional materials comply with the agency moving forward." According to CW1, however, Abiomed senior management did not take the warning letter seriously and "trivialized the FDA concerns." CW2, "a senior quality compliance

[3] The FDA subsequently revised its position on the slogan, "stat[ing] that [it] had decided to leave the tagline issue alone" and asking only that the company not claim that the Impella 2.5 could "Recover Heart Muscle."

and validation engineer at Abiomed from April 2008 through March 2011," likewise said that "Abiomed 'didn't change anything' after being notified by the FDA."

In July 2011, at Abiomed's request, the FDA held a "clarification call" with Abiomed to discuss the Warning Letter. The FDA reminded Abiomed of the Impella 2.5's very limited clearance and told them to refrain from comparing the device to the IABP. One agency member noted that Abiomed "should have had some awareness of the issues given" the January 2010 Untitled Letter.

In August 2011, Abiomed sent a formal response letter to the FDA discussing the actions it had taken to address the FDA's concerns. The company stated that it would not run the balloon advertisement again and would ensure that the advertisement did not exist on Abiomed's website, and that it had removed materials related to the cardiovascular conference from the website. The letter also stated that Abiomed would put into place a plan to prevent future violations. Abiomed did not receive any follow-up correspondence from the FDA for several months.

3. The Off-Label Marketing Allegedly Continues

Plaintiffs allege that, even in the wake of the June 2011 Warning Letter, Abiomed continued to "engage[] in pervasive off-label marketing of the Impella 2.5 beyond its FDA cleared indications." For example, during a February 2012 episode of the CNBC program "Mad Money," Minogue suggested that the Impella 2.5

could be used in patients experiencing heart attacks, and he held up an IABP and an Impella 2.5 side by side and stated that the latter was "cost effective." Also, Abiomed made repeated claims in SEC filings and conference calls regarding the efficacy of the Impella 2.5 based on the results of the Protect II Study.

Plaintiffs also allege that Abiomed trained its sales and clinical staff to compare the Impella 2.5 to the IABP and to "prompt and steer physicians to ask about off-label uses of the Impella 2.5." CW1 and CW5, a "clinical representative at Abiomed from February 2012 until February 2013," said they were provided with "talking points" about the Protect II Study and encouraged to "discuss the superiority of the Impella 2.5 over the IABP." CW2 stated that Abiomed senior management "knew Abiomed did not have the clinical studies to support the claims they were making." CW3, "an account manager at Abiomed from September 2008 until the end of March 2011," relayed similar concerns to senior management and was "blown off." CW7, "a director of clinical operations for Abiomed . . . from February 2009 until November 2011," stated that Abiomed promoted the Impella 2.5 for use in procedures that take longer than six hours. CW4, "a clinical representative in cardiology at Abiomed . . . from August 2007 until September 2010,"

stated that Abiomed "help[ed] doctors identify candidates to use the Impella 2.5 on, including high-risk PCI patients."[4]

On February 24, 2012, Abiomed and the FDA "had a meeting, in part to discuss Abiomed's improper marketing practices." Plaintiffs allege that Abiomed "never disclosed the true purpose of this meeting," instead stating in a later filing with the SEC that the meeting was held to "present the final results of the Protect II Study" and to discuss other unrelated matters.

4. The April 2012 Letter

In April 2012, the FDA sent another letter to Abiomed asserting that its promotional materials were still improperly marketing the Impella 2.5. The FDA noted that the "AbiomedImpella" YouTube channel included several videos discussing unapproved uses of the Impella 2.5, and that the company's website contained a link to "Patient Stories" describing unapproved uses of the device. The agency also objected to Minogue's statements on the "Mad Money" episode. The letter stated that these examples "represent[ed] a fraction of the objectionable claims regarding the Impella," and the agency threatened enforcement action "absent prompt and effective corrections."

[4] Plaintiffs include these allegations in the section of the complaint detailing Abiomed's allegedly improper marketing after the Warning Letter was issued, but they do not provide any indication of the specific time period to which the confidential witnesses' observations correspond.

Abiomed disclosed this FDA letter in its 2012 10-K, filed with the SEC on June 4, 2012. The company announced that it had "received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations" and that it was "cooperating with the FDA in addressing its concerns."

5. The August 2012 Meeting with the FDA and Subsequent Compliance Audits

On August 7, 2012, the FDA and Abiomed met again, again at Abiomed's request. "[T]he primary objective of the meeting was to present Abiomed's actions to close-out the Warning Letter and maintain compliance and then have a discussion as to whether Abiomed was meeting FDA requirements." After Abiomed detailed the measures it was taking to ensure compliance with the regulations, an FDA representative "suggested that Abiomed 'take a step back'" because "[h]e saw the corrective actions as too targeted, and not addressing the whole labeling program." Another representative commented that the FDA did "not think of the clearances of the product in the same way Abiomed does." The FDA was "frustrated" because it felt that regulatory violations were "happen[ing] repeatedly." Minogue responded that "Abiomed had to comply, and will comply," but that, because Abiomed was such a small company, it was "critical to market the device." An FDA representative opined that "it would involve 'walking a fine line' to stay in compliance while marketing." The meeting closed with the FDA

admonishing Abiomed that it took the matter "very seriously," "that a Warning Letter is the last communication given, [and] that Abiomed needed to do a systemic review of its procedures in order to give the [agency] a systemic response for compliance."

In the late summer of 2012, the FDA conducted a compliance audit of Abiomed, and Abiomed simultaneously conducted its own internal audit. After those audits, Abiomed pulled its marketing and training materials "for compliance reasons" and did not put up replacement materials for several months. The replacement materials, according to CW5, were "extremely limited compared to what they had previously" -- for example, they no longer included slides about the Protect II Study. Abiomed confirmed in a letter to the FDA dated August 20, 2012, that it understood its prior approach to compliance was "too narrow in focus" and so was "adopting a broad, systemic approach to address the issues raised by FDA." This approach included "destroy[ing] the Impella marketing brochures cited by FDA, stopp[ing] distribution of all marketing labeling, recall[ing] all marketing labeling held by Abiomed field personnel, and stopp[ing] any planned updates to all labeling and the [Abiomed] website."

6. The U.S. Attorney's Office Investigation

On November 1, 2012, Abiomed disclosed that the U.S. Attorney's Office for the District of Columbia had begun an investigation into its marketing and promotional practices

regarding the Impella 2.5. "Abiomed also maintained its Impella revenue guidance at approximately 30% for the fiscal year, despite 45% growth through the first half of the year, implying a marked slowdown during the second half of the year . . . ." Minogue disclosed the FDA's compliance audit in a conference call conducted the same day and stated that Abiomed "ha[d] taken extensive actions to correct [its] noted compliance issues identified in [its] annual report." Abiomed's stock price fell from $19.82 per share to $13.61 per share on November 1, a drop of approximately 32%.

7. The February 2013 FDA Close-Out Letter

On February 19, 2013, the FDA issued a "Close-Out Letter" to Abiomed stating that the agency had completed its evaluation of Abiomed's corrective actions taken in response to the Warning Letter and had determined that Abiomed had adequately addressed those violations. Abiomed's stock price recovered from the November 2012 fall. As of May 20, 2013, the stock was trading at $23.11 per share.

E. Defendants' Allegedly False and Misleading Statements

Plaintiffs allege that, between August 4, 2011, and October 31, 2012, defendants made specific false and misleading statements that "deceived the investing public" and caused the plaintiffs to purchase Abiomed stock at artificially inflated prices. These statements fall into three principal categories.

First, plaintiffs allege that several of defendants' statements about the growth of Impella product revenues were false and misleading because Abiomed "failed to disclose that the reported revenue growth was substantially the result of off-label marketing." Defendants either provided no explanation for the growth or attributed the revenues to sources such as "increased Impella 2.5 utilization in the cath lab." Plaintiffs allege these statements were misleading because "they failed to disclose that Abiomed's continued revenue . . . was at risk should the Company be forced to discontinue [its marketing] practices." Defendants allegedly made these statements in an August 2011 press release and conference call announcing Abiomed's first quarter 2012 ("Q1 2012") earnings; in Abiomed's Q1 2012 10-Q; in a November 2011 press release and conference call announcing Abiomed's Q2 2012 earnings; in Abiomed's Q2 2012 10-Q; in a February 2012 press release and conference call announcing Abiomed's Q3 2012 earnings; in Abiomed's Q3 2012 10-Q; in a May 2012 press release and conference call announcing Abiomed's Q4 2012 earnings; in Abiomed's 2012 Form 10-K; and in an August 2012 press release and conference call announcing Abiomed's Q1 2013 earnings.

Second, defendants allegedly continued to compare the Impella 2.5 to the IABP based on the results of the Protect II Study, even though FDA regulations prohibited Abiomed from doing so. For example, plaintiffs cite Minogue's statements in an August

2011 conference call that, according to the study, Impella patients "had significantly better outcomes at 90 days" relative to IABP patients. Defendants allegedly made similar statements in Abiomed's Q1 2012 10-Q; in Abiomed's Q2 2012 10-Q; in a February 2012 press release and conference call concerning Abiomed's Q3 2012 results; on the February 7, 2012, episode of Mad Money; in Abiomed's 2012 Form 10-K; and in an August 2012 conference call. Plaintiffs also allege that Abiomed's May 2012 disclosure of the February 24, 2012, meeting with the FDA was false and misleading because it "failed to disclose that the purpose of the meeting was to discuss Abiomed's improper marketing of the Impella 2.5 . . . and the FDA's safety concerns with the device related to the Protect II Study."

Third, plaintiffs allege that many of defendants' statements concerning the regulatory back-and-forth between Abiomed and the FDA were false and misleading. Defendants claimed that Abiomed policy was to refrain from off-label marketing and that Abiomed was taking steps to resolve the FDA's concerns, but in fact Abiomed was "engaged in widespread management-directed off-label marketing and promotion of the Impella 2.5 . . . and was not properly addressing the FDA's issues." In particular, plaintiffs cite the following statement, some version of which was contained in Abiomed's Q1 2012 10-Q, Q2 2012 10-Q, and Q3 2012 10-Q:

> Although our policy is to refrain from statements that could be considered off-label

> promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In June 2011, we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We have cooperated with the FDA in addressing its concerns and believe that we have resolved the matter without any penalties. Although we believe that this issue has been resolved, if similar matters come up in the future, we may not be able to resolve them without facing significant consequences.

Abiomed's 2012 Form 10-K, filed on June 4, 2012, used similar language, and added:

> [I]n April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. We are cooperating with the FDA in addressing its concerns. While we hope to be able to resolve this matter without incurring penalties, we may not be able to resolve it, or any similar matters that may come up in the future without facing significant consequences. Such matters could result in reduced demand for our products and would have a material adverse effect on our operations and prospects.

Finally, the complaint alleges that the certifications of Minogue and Bowen contained in the Form 10-Qs and the Form 10-K were false and misleading because the forms did not "fairly present in all material respects the financial condition [of Abiomed], including the reliance on off-label marketing, and that the revenue and growth reported therein was the result of undisclosed, illicit and unsustainable off-label marketing."

Plaintiffs make additional allegations that they argue bolster the inference that defendants had the requisite scienter (that is, that they had the conscious intent to defraud investors or acted with a high degree of recklessness). First, they contend that Minogue, Bowen, and other senior Abiomed executives sold an uncharacteristically large amount of stock during the Class Period. Minogue allegedly sold 586,149 shares of Abiomed stock, representing 48% of his holdings, for a total of $9,636,124 from January 2010 through the end of the Class Period. Bowen sold 57,919 shares, representing 6.5% of his holdings, for $1,302,878 during that period, after having sold no stock before January 2010. Plaintiffs cite similar figures for five other non-defendant Abiomed executives, who collectively earned approximately $5.6 million by selling stock during this period.

Defendants counter that many of the trades cited by plaintiffs were made pursuant to 10b5-1 plans which were entered into before the Class Period (August 4, 2011, to October 31, 2012) and Minogue in fact increased his holdings of Abiomed stock during the Class Period. Defendants also counter that the reason Bowen made no trades prior to the cited period was because he only became eligible to trade Abiomed stock during that period.

Plaintiffs also allege that, because the Impella 2.5 was part of Abiomed's "core business," Minogue and Bowen must have been aware of the fact that Abiomed was unlawfully promoting the device,

and that "the pervasiveness of the illicit and off-label marketing and promotion of the Impella 2.5 . . . further supports a strong inference of scienter."

F. Summary

Distilled to its essence, plaintiffs' complaint tells the following story: For a 38-month period, beginning with the FDA's Untitled Letter in January 2010 and ending with the FDA's Close-Out Letter in February 2013, the FDA repeatedly raised concerns that Abiomed's marketing of the Impella 2.5 did not comply with applicable regulations. Abiomed responded to these concerns by making limited changes to its promotional tactics, but the FDA was not satisfied until the summer of 2012, when Abiomed conducted an internal compliance audit and pulled all of its marketing and training materials, to be replaced with entirely new ones. Confidential witnesses cited in the complaint state that Abiomed's senior management was aware that its promotional practices before that audit were in violation of FDA regulations and willfully chose not to alter them. We note that might raise issues under FDA regulations.

What raises securities law concerns, according to plaintiffs, is that management allegedly misled investors during this period by (1) failing to attribute the growth in Impella revenues to unlawful off-label marketing practices; (2) improperly comparing the Impella 2.5 to the IABP by touting the results of the

Protect II Study; (3) stating that it had a policy of not engaging in off-label marketing; and (4) stating that Abiomed was taking steps to address the agency's concerns, when in fact the company was engaged in intentional and pervasive off-label marketing, contrary to its stated policy.

II. Litigation Procedural History

On November 16, 2012, two individuals filed a complaint on behalf of all purchasers of Abiomed stock during the Class Period. Simon, 2014 WL 1413638, at *10. In February 2013, the district court appointed the two appealing institutional investors as lead plaintiffs, and the lead plaintiffs filed an amended complaint on May 20, 2013. Id.

On April 10, 2014, the district court, in a thorough opinion, granted defendants' motion to dismiss. The court found that plaintiffs had plausibly alleged that Abiomed engaged in off-label marketing practices and that those practices materially affected the stock price. Id. at *12-16. It also held that the plaintiffs had plausibly alleged several actionable misrepresentations: (1) Abiomed's statements that its policy was to refrain from off-label marketing; (2) Abiomed's statements that Impella revenue growth was attributable to "particular primary source[s]" other than off-label uses; and (3) Abiomed's statements about the Protect II Study "[t]o the extent [they were made] to promote off-label marketing." Id. at *16-20. However, the court

found that the complaint's allegations of scienter were not "cogent and compelling," as is required for pleadings in securities fraud cases. Id. at *20-23. The court also dismissed plaintiffs' § 20(a) claims because such a violation "depend[s] on an underlying violation of the Exchange Act." Id. at *23.

This appeal followed. Plaintiffs argue that the district court erred in holding that they failed to adequately plead scienter and that the court should have granted them leave to file an amended complaint.

III. Section 10 and Rule 10b-5 Claim

A. Legal Standard

"Section 10(b) of the Securities Exchange Act of 1934 forbids the 'use or employ, in connection with the purchase or sale of any security . . ., [of] any manipulative or deceptive device . . . ." Tellabs, Inc. v. Makor Isssues & Rights, Ltd., 551 U.S. 308, 318 (2007) (first and second alterations in original) (quoting 15 U.S.C. § 78j(b)). SEC Rule 10b-5 implements that statute by making it unlawful, inter alia,

> [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading, or . . . [t]o 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.

Id. (second alteration in original) (quoting 17 C.F.R. § 240.10b-5) (internal quotation marks omitted).

"To state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Deka Int'l v. Genzyme Corp. (In re Genzyme Corp. Sec. Litig.), 754 F.3d 31, 40 (1st Cir. 2014).

The PSLRA requires a securities fraud complaint to "'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" ACA Fin., 512 F.3d at 58 (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). While this case turns on scienter, we also discuss the requirements for materiality, as the materiality and scienter inquiries are linked. See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 756-58 & n.2 (1st Cir. 2011). "A fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing] the total mix of information made available.'" Id. at 756 (alteration in original) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (internal quotation marks omitted)). "A statement can be 'false or incomplete' but not actionable 'if the misrepresented fact is otherwise insignificant.'" Id. at 756-57 (quoting Basic, 485 U.S. at 238).

"The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter." ACA Fin., 512 F.3d at 58. "Scienter is a 'mental state embracing intent to deceive, manipulate, or defraud.'" Waters Corp., 632 F.3d at 757 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). 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." Id. (citations omitted) (internal quotation marks omitted); accord ACA Fin., 512 F.3d at 58-59. Recklessness, as used in this context, "does not include ordinary negligence, but is closer to being a lesser form of intent." Greebel v. FTP Software, Inc., 194 F.3d 185, 188 (1st Cir. 1999).

An inference of scienter is "strong" if "a reasonable person would deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. "When there are equally strong inferences for and against scienter, the draw is awarded to the plaintiff." Waters Corp., 632 F.3d at 757. "[S]cienter should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." ACA Fin., 512 F.3d at 59. "There is no set pattern of facts that will establish scienter; it is a case-by-

case inquiry." Id. at 66. We review de novo the district court's dismissal of the complaint for failure to state a claim. Id. at 58.

Plaintiffs seize on several purported legal errors made by the district court. They argue, for example, that the district court had an erroneous conception of the scienter required for a violation of the securities laws, failed to make a recklessness finding, and failed to properly weigh competing evidence. Since our review of the dismissal is de novo, however, we need not attend separately to each of these arguments.[5] Instead, we explain why we

[5] We are skeptical of the merits of the arguments, in any event. Plaintiffs contend that the district court erroneously required them to show that defendants had actual knowledge that their representations or omissions were misleading. But the court stated the correct standard ("a conscious intent to defraud or a high degree of recklessness") at the outset of its scienter discussion. Simon, 2014 WL 1413638, at *20. True, the court then stated that the defendant must have "actual knowledge that the representation of omission was misleading," see id. at *20-21, but the focus on actual knowledge almost certainly reflects the fact that plaintiffs' theory of the case consistently has been that the higher-ups at Abiomed knew full well that what they were doing was wrong, and yet did it anyway. Plaintiffs have not relied on a recklessness theory, and it is thus unsurprising that the district court spent little space in its opinion on the concept of recklessness.

Plaintiffs also argue that the district court found that the inferences for and against scienter were equally strong and erroneously awarded that tie to the defendant. This contention wrests loose language from the district court's opinion out of context. The court did state that "it is equally reasonable to infer that senior management was merely negligent, inattentive, or even incompetent, rather than engaged in deliberate acts of securities fraud," id. at *21, and that the insider sales provided "at best equivocal support of the proposition that defendants intended to defraud investors," id. at *23. But elsewhere, the court correctly stated that a "tie goes to the plaintiff," id. at *11, and its analysis, considered as a whole, shows that the inference of scienter was in fact less plausible than competing

agree with the district court's ultimate conclusion that plaintiffs' complaint fails to state a claim under the PLSRA's pleading standards.[6] See Bryceland v. Minogue, 557 F. App'x 1, 3 (1st Cir. 2014) (Souter, J.) ("[B]ecause our review of the dismissal . . . is de novo, rather than answer each of [plaintiff]'s assignments of error, it will suffice to highlight the deficiencies in her complaint." (citation omitted)); cf. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 84 (1st Cir. 2002) (noting that an appellate court may affirm a district court's decision on any grounds supported by the record). Plaintiffs have failed to show that defendants made the challenged statements with a conscious intent to defraud or with a high degree of recklessness.

B. Application

Plaintiffs allege that defendants made the following misrepresentations that deceived investors: (1) statements about growth in Impella revenues that did not disclose that the growth was due to off-label marketing; (2) statements about the 90-day results of the Protect II Study that improperly compared the

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inferences. Cf. Connor B. ex rel Vigurs v. Patrick, 774 F.3d 45, 54 n.9 (1st Cir. 2014) (determining, based on a reading of the district court's opinion as a whole, that the "court did not misapprehend the correct [legal] standard," despite some isolated language suggesting otherwise).

[6] Our discussion applies to the scienter analysis with respect to the individual defendants, Minogue and Bowen, as well as the corporate defendant, Abiomed.

Impella 2.5 to the IABP; (3) statements that Abiomed had a policy of not engaging in off-label marketing; and (4) statements that Abiomed was taking steps to address the FDA's concerns, when in fact the company was engaged in intentional and pervasive off-label marketing, contrary to its stated policy. Plaintiffs' counsel conceded at oral argument that plaintiffs' case depends on the first, third, and fourth categories of statements. Statements in the second category are simply examples of improper off-label marketing; those are relevant to this case only insofar as they show that the defendants' statements that they were not engaged in off-label marketing were untrue.[7]

We therefore focus on defendants' statements about increased Impella revenues and their statements that Abiomed's policy was to comply with FDA regulations concerning off-label marketing and that the company was taking steps to address the agency's concerns regarding promotion of the Impella 2.5. We address the revenue-related statements first, then turn to the statements regarding Abiomed's interactions with the FDA, and finally address the complaint's insider trading allegations.

1. Statements Regarding Increased Revenues

[7] The district court reached the same conclusion. See Simon, 2014 WL 1413638, at *20 (finding that, "[t]o the extent that defendants made statements concerning the Protect II study in order to promote off-label marketing, the statements may be actionable" because Abiomed claimed that it did not engage in off-label marketing, "[b]ut to the extent defendants simply gave accurate information about the study, it cannot form the basis of a claim of misrepresentation").

We assume arguendo that the district court correctly found that plaintiffs had alleged enough to survive dismissal on claims that Abiomed provided false explanations for Impella revenue growth. See Simon, 2014 WL 1413638, at *17. We hold that the statements are not actionable on scienter grounds. We do address the strength of the materiality of the statements because "[t]he question of whether a plaintiff has pled facts supporting a strong inference of scienter has an obvious connection to the question of the extent to which the omitted information is material." Waters Corp., 632 F.3d at 757. "If it is questionable whether a fact is material or its materiality is marginal, that tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact." Id.

The materiality of the impugned omission here -- Abiomed's failure to state that some of the increased revenues were due to off-label marketing -- is marginal at best. Plaintiffs' contention that the omission would have mattered to a reasonable investor depends on a long chain of inferences, most of which are not sufficiently substantiated by the allegations in the complaint.

First, we would have to infer that, of the 85% of Abiomed revenue due to sales of Impella products, a substantial portion is due to sales of the Impella 2.5. The complaint alleges that the Impella 2.5 accounted for "most" of that revenue, but provides no specifics. Second, we would have to infer that, of the revenues

from the Impella 2.5, a substantial portion was due to purchases for off-label use by health care professionals. The complaint provides no indication of the proportion of Impella 2.5 use that was off-label. Third, we would have to infer that, of the revenues from off-label use, a substantial portion of that use was due to off-label marketing of the device, and, further, that the portion was so significant as to undercut the company's projected growth figures. And fourth, we would have to infer that the resulting undercutting of the growth figures was substantial enough to have a material effect on the stock price. Again, the complaint provides no basis in fact for making these inferences.

Plaintiffs do allege that off-label promotion was widespread, but they do not state or even suggest what proportion of sales were made as a result of such efforts, or the significance of the contribution of those sales to Abiomed's stock price. The marginal materiality of the alleged statements and omissions concerning revenues weighs against an argument that defendants here possessed the requisite scienter. See Waters Corp., 632 F.3d at 757.[8]

[8] Plaintiffs' counsel contended at oral argument that we can infer that Abiomed's failure to disclose its off-label marketing activities was material because the company scaled back its revenue projections on November 1, after it "purged all of its off-label marketing materials." We think that unlikely, but more than that, it is much more plausible to infer that Abiomed lowered its revenue projections in light of the simultaneous announcement that the U.S. Attorney's Office had begun an investigation into the company.

Plaintiffs attempt an argument that defendants made statements about Abiomed's revenues with the intent to deceive investors or with reckless disregard as to whether investors would be deceived. The argument is undercut by the fact that Abiomed explicitly warned investors both (a) that the FDA might disagree with the company's assessment of the legality of its marketing practices and (b) that, if the FDA took enforcement action against it, that "could result in reduced demand for our products and would have a material adverse effect on our operations and prospects." See Genzyme Corp., 754 F.3d at 42-43 (noting that a corporation's informative disclosures "undercut any inference of fraudulent intent on the part of defendants"); Waters Corp., 632 F.3d at 760 ("'[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter.'" (alteration in original) (quoting Ezra Charitable Trust v. Tyco Int'l, Ltd., 466 F.3d 1, 8 (1st Cir. 2006))).

Further, the company did not withhold information about the FDA's concerns once the FDA issued a Warning Letter.[9] Abiomed promptly disclosed receipt of the June 2011 Warning Letter and stated repeatedly throughout the Class Period that the FDA "could

[9] "Section 10(b) does not create an affirmative duty to disclose." Genzyme Corp., 754 F.3d at 41. Thus, there is no per se rule that a company immediately disclose receipt of any correspondence with the FDA. See id. at 42 (holding that a company need not immediately disclose a Form 483 issued by the FDA because it was "merely observational in nature, and d[id] not represent the FDA's final word").

disagree [with Abiomed's position that its marketing was lawful] and conclude that we have engaged in off-label promotion." Abiomed did not promise a positive resolution of the matter; rather, it acknowledged that "if similar matters come up in the future, we may not be able to resolve them without facing significant consequences." These are not the actions of a company bent on deceiving investors as to their future earnings prospects.[10]

Under plaintiffs' theory of the case, Abiomed should have affirmatively admitted widespread wrongdoing rather than stating that the outcome of its regulatory back-and-forth with the FDA was uncertain. That would be a perverse result; such an admission would have been misleading, since the off-label marketing issues had the potential to be resolved with no adverse action from the FDA. We made a similar point in In re Boston Scientific Corp. Securities Litigation, 686 F.3d 21 (1st Cir. 2012), where we noted that "a company may behave 'irresponsibly' if it issues an ominous warning about an uncertain risk that 'had not yet been adequately investigated.'" Id. at 31 (quoting N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 58 (1st Cir.

[10] This court reached a similar conclusion in the parallel derivative action brought by Abiomed shareholders against Abiomed and its directors. See Bryceland, 557 F. App'x at 5 (holding that the shareholders' complaint did not "allege facts showing that the directors hid from investors the trouble that th[e alleged off-label] marketing had created; indeed, as the reproduced sections of Abiomed's SEC filings make clear, the company was not shy in disclosing its exposure to liability").

2008)). There must be some room for give and take between a regulated entity and its regulator.[11]

2. Statements About Abiomed's Policy with Respect to Off-Label Marketing and its Interaction with the FDA

Again, we assume arguendo that "Abiomed had an actual policy or practice of off-label marketing, while its public statements were that its policy was to refrain from such marketing," Simon, 2014 WL 1413638, at *17, and that defendants stated that they were cooperating with the FDA when they were not doing so. But we conclude that plaintiffs have failed to allege that defendants made these statements with the requisite scienter.

First, there are Abiomed's substantial disclosures about its correspondence with the FDA. As said, these disclosures undercut any inference of scienter. Plaintiffs' brief glosses over these disclosures in an effort to make the case for scienter more compelling. According to the brief, Abiomed said that it did not engage in off-label marketing and that all of the FDA's concerns "had been resolved." But this characterization is inaccurate, both as to the complaint and as to what the actual statements were. The complaint actually says that Abiomed stated its policy was to "refrain from statements that could be considered off-label

[11] That the company did not disclose the receipt of the Untitled Letter from the FDA is not proof of scienter. The FDA gradates its levels of inquiry and does not itself make Untitled Letters public.

promotion," but that the FDA could disagree with Abiomed's view on that question; and that while it "believe[d]" the issue had been resolved, it could come up again in the future and could entail "significant consequences." In resolving this appeal, we focus, as did the district court, on the allegations of the complaint, not on plaintiffs' characterization of those allegations.

Other evidence supports Abiomed's argument that it was not involved in a scheme to defraud investors but rather in finding a solution amenable to the FDA while meeting its need to market its products. It was Abiomed which asked for meetings with the FDA. And an agreement was reached. The FDA in fact sent a close-out letter in February 2013 saying that Abiomed's corrective actions undertaken in response to the June 2011 Warning Letter had adequately addressed the FDA's concerns. This significantly undercuts any inference that defendants purposefully or recklessly misled investors about the extent of Abiomed's cooperation with the FDA.

Scienter is not established because there were statements from confidential witnesses that Abiomed management was in fact intentionally violating FDA regulations. These witnesses said that Abiomed senior management knew that Abiomed was improperly marketing the Impella 2.5, did not take the FDA's warnings

seriously, and "blew off" the concerns of lower-level employees.[12] The confidential witnesses are not described with sufficient particularity for their statements to give rise to the requisite "strong inference" of scienter on the part of Abiomed and its management. As the district court noted, none of the witnesses "were in senior management positions, and they appear to have had relatively little ongoing contact with senior management." Simon, 2014 WL 1413638, at *14. CW2, CW3, CW4, and CW6 did not even work at Abiomed during the Class Period and so would not have had firsthand knowledge of the state of mind of Abiomed's management during that period. And CW1, CW5, and CW7, who stated that the training and marketing materials Abiomed provided were "improper" under FDA regulations, did not identify the time period to which most of their statements related. Cf. Biogen IDEC, 537 F.3d at 52-

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[12] That the witnesses were confidential did not disqualify them.

> [W]here plaintiffs rely on confidential personal sources but also on other facts, they need not name their sources as long as the latter facts provide an adequate basis for believing that the defendants' statements were false. Moreover, even if personal sources must be identified, there is no requirement that they be named, provided they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.

Mesko v. Cabletron Sys., Inc. (In re Cabletron Sys., Inc.), 311 F.3d 11, 29 (1st Cir. 2002) (alteration in original) (quoting Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)).

53 (discounting probative value of observations by confidential sources in part because the sources did not disclose when those observations were made). The CWs' statements are also undermined by the fact that the FDA eventually closed out its investigation of Abiomed without taking any action adverse to the company.

More fundamentally, even if the CWs' statements plausibly suggest that Abiomed was acting improperly, they do not show that defendants' statements about company policy and the FDA's inquiries were made with conscious intent to defraud or recklessly. As we said in Waters Corp., "[t]he key question . . . is not whether defendants had knowledge of certain undisclosed facts, but rather whether defendants knew or should have known that their failure to disclose those facts 'present[ed] a danger of misleading buyers or sellers.'" 632 F.3d at 758 (third alteration in original) (emphasis added) (citation omitted) (quoting Greebel, 194 F.3d at 198). For example, CW7's statements, far from suggesting an intent to defraud investors, suggest instead that Abiomed was aggressively marketing the Impella 2.5 "every which way" in order to sell more units.[13]

3. Insider Trading Allegations

The plaintiffs' allegations of insider trading do not alter our conclusion as to lack of scienter. "Depending on

[13] At oral argument, plaintiffs' counsel disavowed any reliance on the argument, based on an efficient market hypothesis, that any statements regarding the Impella 2.5 aimed at potential buyers of the device were also effectively aimed at investors in Abiomed.

context, allegations of insider trading may offer some support for inferences of scienter." Waters Corp., 632 F.3d at 760. "'The vitality of the inference to be drawn depends on the facts, and can range from marginal to strong.'" Id. (quoting Greebel, 194 F.3d at 197–98). For stock sales by corporate officials to bolster an inference of scienter, the trading must be, "[a]t a minimum, . . . unusual, well beyond the normal patterns of trading by those defendants." Id. at 761 (quoting Greebel, 194 F.3d at 198) (internal quotation marks omitted); accord Greebel, 194 F.3d at 206-07 (sales must be "out of the ordinary or suspicious").

Here, the trading cited in the complaint was neither unusual nor suspicious. Minogue increased his holdings of Abiomed stock by 9.2% during the Class Period, which negates any inference that he had a motive to artificially inflate Abiomed's stock during that period. Cf. ACA Fin., 512 F.3d at 66-67 (declining to find a strong inference of scienter in part because defendants would not have been personally enriched by defrauding investors). Bowen made his first sales of Abiomed stock (totaling 6.5% of his holdings) between January 2010 and the end of the Class Period. But those sales are hardly suspicious given that he had just joined the company in December 2008 and first became eligible to trade in December 2009.[14] Plaintiffs list the amounts of stock sales made

[14] We need not address the parties arguments concerning defendants' 10b5-1 trading plans because plaintiffs' arguments concerning the purported insider trading fail even without

by other senior executives during that period, but they do not provide sufficient evidence about those trades to allow the court to draw from them a strong inference of scienter. For example, the complaint is silent as to the percentage of holdings sold or the circumstances surrounding the trades. It is also unclear whether all of the cited executives would have had detailed knowledge about Abiomed's marketing practices. Cf. Waters Corp., 632 F.3d at 762 n.5 (finding that allegations regarding non-defendant insider sales were not probative because the complaint listed "only bare facts about the shares sold").

4. Conclusion

Abiomed's promotional and marketing activities for its core product might have been a risky course in terms of its likelihood of prompting sanctions from the FDA. Still, "[a]llegations of corporate mismanagement are not actionable under Rule 10b-5. Nor are allegations of mere negligence." Id. at 760 (citations omitted); see also Greebel, 194 F.3d at 188 (noting that the mens rea required for securities fraud "does not include ordinary negligence, but is closer to being a lesser form of intent"). As the district court correctly noted, "this case is not about whether or not defendants violated the FDCA or FDA regulations. It concerns alleged violations of securities

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considering those plans.

law . . . ." Simon, 2014 WL 1413638, at *14. Plaintiffs' Rule 10b-5 claim fails.

IV. Section 20(a) Claim

Section 20(a) of the Securities Exchange Act imposes joint and several liability on persons in control of entities that violate securities laws. 15 U.S.C. § 78t(a). A section 20(a) claim is derivative of an underlying violation of the securities laws. ACA Fin., 512 F.3d at 67-68. Because the district court correctly dismissed plaintiffs' claims under Rule 10b-5, it also correctly dismissed plaintiffs' section 20(a) claims. See id.

V. Leave To Amend

On a hopeless quest, plaintiffs argue we should remand to allow them amend the complaint. No proper request was made to the district court, only a mention in a footnote in their opposition to dismissal. See Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 220 (2d Cir. 2006) ("It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss."), abrogated on other grounds by F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013); Calderon v. Kan. Dep't of Soc. & Rehab. Servs., 181 F.3d 1180, 1185-87 (10th Cir. 1999) (noting with approval an earlier holding that a district court need not grant leave to amend if plaintiffs make a "bare request in their response to a motion to dismiss").

In any event, it is far too late; plaintiffs were put on notice of the deficiencies in the complaint by the motion to dismiss. If they had something relevant to add, they should have moved to add it then. See ACA Fin., 512 F.3d at 57 (rejecting plaintiffs' argument that the district court erred in denying them leave to amend because "[p]laintiffs took no action to add new allegations" in response to defendants' motion to dismiss "even though they knew what they would add if they amended," and noting that allowing such a practice would "lead to delays, inefficiencies, and wasted work"). And even now there is no suggestion that amendment would be anything other than futile. See, e.g., HSBC Realty Credit Corp. (USA) v. O'Neill, 745 F.3d 564, 578 (1st Cir. 2014); Braunstein v. McCabe, 571 F.3d 108, 127 (1st Cir. 2009); Universal Commc'n Sys., Inc. v. Lycos, Inc., 478 F.3d 413, 418 (1st Cir. 2007). We wish to discourage this practice of seeking leave to amend after the case has been dismissed.

VI. Conclusion

We affirm the judgment of the district court. Costs are awarded to Abiomed.