United States Court of Appeals
For the First Circuit

No. 07-1794

MISSISSIPPI PUBLIC EMPLOYEES' RETIREMENT SYSTEM,

Plaintiff, Appellant,

v.

BOSTON SCIENTIFIC CORPORATION; James R. Tobin; Paul A. LaViolette; Fredericus A. Colen; Lawrence C. Best; Stephen F. Moreci; Robert G. MacLean; Peter M. Nicholas; Paul W. Sandman; James H. Taylor, Jr.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. Joseph L. Tauro, U.S. District Judge]

Before
Torruella, Circuit Judge,
Tashima, Senior Circuit Judge,[*]
and Lynch, Circuit Judge.

Carolyn G. Anderson with whom Timothy J. Becker, Anne T. Regan, Zimmerman Reed, P.L.L.P., David S. Nalven, Steve Berman, Hagens Berman Sobol Shapiro, LLP, Richard A. Lockridge, Gregg M. Fishbein, Lockridge Grindal Nauen, P.L.L.P., Mike Moore, and Moore Law Firm were on brief for appellant.

Stuart J. Baskin with whom John Gueli, Kirsten M. Nelson, Shearman & Sterling LLP, William H. Paine, Timothy J. Perla, and Wilmer Cutler Pickering Hale & Dorr LLP were on brief for defendants.

[*] Of the Ninth Circuit, sitting by designation.

April 16, 2008

LYNCH, Circuit Judge. This securities case was brought against Boston Scientific, a publicly traded manufacturer of medical devices based in Natick, Massachusetts. The appeal concerns dismissal of claims based on the company's launch of a new product, the drug-eluting TAXUS coronary stent, and its eventual recalls. Plaintiff, a Mississippi pension fund and purchaser of Boston Scientific stock, alleges that company executives both withheld material information about problems with the stent and decisions addressing those problems, and made misleading positive statements, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and the attendant rules and regulations, including Rule 10b-5, 17 C.F.R. § 240.10b-5.

Plaintiff appeals the district court's grant of defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). The district court held, in a thoughtful decision, that plaintiff failed to meet the heightened pleading requirements imposed by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737. In re Boston Scientific Corp. Sec. Litig., 490 F. Supp. 2d 142, 152, 162 (D. Mass. 2007).

Applying the standards recently articulated by the Supreme Court in Tellabs, Inc., v. Makor Issues & Rights, Ltd., ___ U.S. ___, 127 S. Ct. 2499 (2007), and by this court in ACA

Financial Guaranty Corp. v. Advest, Inc., 512 F.3d 46 (1st Cir. 2008), we hold that plaintiff has pled claims sufficient to withstand a motion to dismiss and so we remand the case. Our remand permits the court, should it choose to do so, to allow a limited discovery period on the issues raised. See, e.g., Greebel v. FTP Software, Inc., 194 F.3d 185, 188 (1st Cir. 1999); Gross v. Summa Four, Inc., 93 F.3d 987, 990 (1st Cir. 1996). "Our ruling does not mean that plaintiffs' claims have any merit. It means only that the claims are not to be dismissed at this very early stage. Nothing has been proven yet." In re Cabletron Sys., Inc., 311 F.3d 11, 20 (1st Cir. 2002).

I.

On September 23, 2005, the Public Employees' Retirement System of Mississippi ("PERS") brought suit in federal district court as the lead plaintiff in a class action against Boston Scientific and company executives Peter M. Nicholas (Chairman of the Board of Directors); James R. Tobin (President and Director); Paul A. LaViolette (Chief Operating Officer and member of the Executive Committee[1]); Fredericus A. Colen (Senior Vice President and Chief Technology Officer); Lawrence C. Best (Senior Vice President and Chief Financial Officer); Stephen F. Moreci (Senior Vice President and Group President of Endosurgery); Robert G.

[1] LaViolette became Chief Operating Officer in 2004, after the beginning of the class period.

MacLean (Vice President of Human Resources); Paul W. Sandman (Senior Vice President, Secretary, and General Counsel); and James H. Taylor, Jr. (Senior Vice President of Corporate Operations). Consolidated Am. Compl. ("CAC") ¶¶ 1, 15-23.

Plaintiff sued on behalf of a putative class of individuals and entities who purchased equity securities in Boston Scientific from March 31, 2003 to August 23, 2005. Id. ¶ 1. Plaintiff alleged that during that period, defendants made false and misleading statements and caused the market price of the company's securities to be artificially inflated, both harming investors and allowing the individual insider defendants to enrich themselves in excess of $332 million. Id.

Plaintiff's original complaint divided into four categories its allegations regarding defendants' statements about a civil lawsuit with Medinol Ltd., a Department of Justice investigation into a 1998 product recall, the company's introduction of TAXUS stents to the market, and FDA investigations and warnings regarding Boston Scientific's plants. Only the TAXUS stent issue is before us on appeal following the dismissal of all claims.

In particular, plaintiff advances these theories. By late 2003 defendants became aware of serious problems in patients in Europe resulting from the insertion of the new TAXUS stent, not yet introduced in the United States. The TAXUS stent was

introduced in the United States in March 2004; American doctors reported similar problems. In the spring of 2004 defendants made affirmative statements attributing the problems reported about the new TAXUS stent to the unfamiliarity of doctors with the new stent. They did not correct the statements even though they had become aware that the problem was not doctor unfamiliarity, but rather a manufacturing defect in the stent that caused the balloon to fail to deflate. Defendants continued to withhold information about a manufacturing change Boston Scientific had instituted in December 2003 which would address the defect. They withheld the information to build up inventory, in order to preserve market share, before announcing recalls of TAXUS stents based on the potential defects. Meanwhile, while withholding this material information, several of the individual defendants traded on the open market in unusual patterns and unusual amounts. When the material information was finally and belatedly disclosed, the market price for Boston Scientific stock plummeted downward. The stock price dropped 7.6% after the company announced an expanded recall and revealed that three deaths and several dozen serious injuries had been connected to balloon deflation failure, and it dropped another 6.6% when the company expanded the recall of the TAXUS stent for a second time. CAC ¶¶ 100, 102.

The defendants' theory is that at the time the company received some thirty to forty reports of problems in Europe of

balloon non-deflation following stent insertion, it was unable to identify anything about the device itself that would cause the problem and attributed the problem to doctor unfamiliarity. Defendants' brief argues that independently and

> [i]n an effort to improve the device, Boston Scientific tried completely to eliminate the possibility of balloon non-deflation. It eventually identified a means to do so, by changing the manner of bonding the delivery catheter to the balloon and by implementing an additional inspection test at the end of the manufacturing process. These proposed modifications were submitted to the FDA for approval in April 2004 and approved by the FDA the following month. In June 2004 Boston Scientific began manufacturing the "new" device.
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> After it identified how to completely eliminate what was already an infrequently occurring issue, Boston Scientific was able to re-analyze its "old" Taxus inventory. That process led to the identification of specific lots that had the potential for non-deflation. Out of an abundance of caution, Boston Scientific voluntarily recalled a limited number of specific production lots of its "old" Taxus stents in July and August 2004.

It is the company's position that the changes would have been implemented "whether it got a complaint or not." The removal of the possibility that the balloon would fail to deflate by the manufacturing change did not prove there was a defect, much less that the company knew at an earlier date of a connection between the manufacturing change and the problem that necessitated the recalls, or that it was obliged to disclose it.

A. Plaintiff's Allegations

Plaintiff brought the suit as a putative class action. The class period plaintiff claims is relevant to this narrowed appeal is December 2, 2003 to August 5, 2004.

In 2001, Boston Scientific decided to produce a drug-eluting stent[2] to compete with a similar product manufactured by Johnson & Johnson. CAC ¶ 86. Boston Scientific's product is known as TAXUS® Express Paclitaxel-Eluting Monorail® Coronary Stent System. Id.

TAXUS debuted in Europe in January 2003. Id. ¶¶ 87, 92. Plaintiff alleges that defendants felt "tremendous pressure" to introduce TAXUS into the U.S. market because the company was losing market share to Johnson & Johnson. Id. ¶ 87. While in the process of obtaining final FDA approval for TAXUS, defendants allegedly downplayed news that could delay the U.S. launch, such as failing to disclose in a timely manner an FDA major deficiency letter that the company received in September 2003. Id. ¶ 89. Meanwhile,

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[2] Coronary stents are tiny tubes placed in patients' arteries to ameliorate blockages and facilitate blood flow. Drug-eluting stents (also called "coated" or "medicated" stents) slowly release drugs aimed at reducing restenosis, a narrowing of the arteries that can occur after a stent is implanted. Stents are implanted in arteries using a delivery catheter.

In 2002, Boston Scientific marketed a coronary stent system called the Express², which combined its highly successful Express™ coronary stent and Maverick® balloon dilation catheter, which uses a tiny balloon to inflate the artery and permit the stent to be inserted. TAXUS uses the same delivery catheter as the Express²; the systems differ in that Express² is a bare metal stent whereas TAXUS is a drug-eluting stent.

defendants "provided to the investment community a drum roll leading up to the FDA's approval of TAXUS which was deafening." Id. ¶ 90. Plaintiff alleges that in anticipation of FDA approval and in response to positive comments made by defendants, analysts upgraded their rating of Boston Scientific stock, and by March 2004, the price of Boston Scientific stock on the New York Stock Exchange hit a new high, trading at over $40 a share. Id. ¶¶ 15-23, 91, 100.

On March 4, 2004, the FDA approved TAXUS for marketing and distribution in the United States. Id. ¶ 92. Plaintiff alleges that Boston Scientific "trumpeted [TAXUS's] immediate impact in the Company's effort to take over market share for stents." Id. Meanwhile, defendants did not disclose complaints they had received from doctors in Europe that the balloon used during insertion of the TAXUS stent did not deflate. Id. ¶ 93. Defendants also knew that the Express² metal stent, upon which the new TAXUS stent was based, "had a history of significant problems." Id.

Despite this knowledge, defendants "minimized and misrepresented . . . problems," including in the company's Form 10-Q for the quarter ending March 31, 2004, which Boston Scientific filed with the SEC on May 7, 2004. This report stated that the company was "reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures."

Id. In meetings with analysts, defendants "further downplayed the complaints" by attributing the problems to doctor unfamiliarity with TAXUS rather than balloon non-deflation. Id.

Meanwhile, plaintiff alleges, defendants knew "the problems with TAXUS were much more significant, based on the complaints they had received out of Europe and the complaints which were rolling in as a result of the product rollout in the United States." Id. ¶ 95. In December 2003 defendants allegedly had begun planning a manufacturing change for TAXUS because they had become aware that the problem with TAXUS was not doctor unfamiliarity but rather a "manufacturing defect." This manufacturing change, which according to defendants was approved by the FDA in May 2004, related to the manner of the laser bonding of the delivery catheter and balloon. Defendants did not disclose this manufacturing change to the public prior to July 2, 2004, when they referred to it in a conference call with analysts. Id. ¶¶ 95, 98. Defendants also discussed the manufacturing change in the press releases announcing subsequent recalls on July 16 and August 5.

Plaintiff alleges that defendants had an obligation to disclose this manufacturing change to the public at some point prior to July 2 because it was necessary to correct defendants' earlier and continuing statements that the adverse reports related to U.S. doctors' unfamiliarity with TAXUS rather than to a defect

with the product itself. As plaintiff put it at oral argument: "The disclosure that we are asking for is that as soon as they learned that . . . the problems with TAXUS were not related to doctor [un]familiarity . . . they had a duty to disclose that."

In the months following the U.S. launch of TAXUS, Boston Scientific's stock price rose and defendants began to sell large quantities of their own stock. CAC ¶ 96. Plaintiff specifically points to the following stock sales, all of which occurred within two months of the FDA's March approval of TAXUS: over $40 million by James R. Tobin; over $54 million by Lawrence C. Best; over $4 million by Fredericus A. Colen; and over $3 million by Robert G. MacLean. Id. Additionally, defendant Paul LaViolette sold approximately $3 million worth of company stock in June of 2004. Id. ¶ 18. Plaintiff argues that these sales demonstrated "unusual patterns" and occurred in "unusual amounts."

On July 2, 2004, Boston Scientific announced that it was voluntarily recalling two lots of TAXUS stents (a total of 200 stents), which had not yet been implanted in patients. Id. ¶ 97. In a press release announcing the recall, the company stated that the FDA had received reports of one death and sixteen serious injuries associated with balloon non-deflation, along with eight reports of balloon malfunction that had not caused injury. Id. The press release explained that the recall was due to "characteristics . . . related to a narrowing in the area where the

catheter and balloon are laser welded," a problem referred to as "focal neckdown." "This narrowing resulted in the potential for impeded deflation and removal of the balloon after stent placement."

The manufacturing change that defendants had put into motion in December 2003 addressed the problem of focal neckdown by changing the manner of the laser welding of the catheter and balloon. In a conference call with analysts on July 2, defendants asserted that this manufacturing change had been in progress before the TAXUS launch and "would have been submitted whether we got a complaint or not." Id. ¶ 98.

Two weeks later, on July 16, defendants voluntarily expanded the company's recall to 85,000 TAXUS stents and 11,000 Express² stents -- which use the same delivery catheter as TAXUS -- and admitted knowing of two additional serious injuries associated with TAXUS as well as two deaths and twenty-five serious injuries associated with balloon deflation failure in Express² stents. Id. ¶ 100. In a press release announcing this recall, defendants assured the public: "The Company implemented review of its manufacturing process, additional inspections, and an FDA-approved modification to the manufacturing process for these products. The current and future production are not expected to experience similar balloon deflation problems."

After defendants announced this expanded recall on July 16, Boston Scientific's stock price dropped $3.09 per share, or 7.6%, to $37.40. Id. ¶ 100. Plaintiff connects the drop in stock price to the revelations of the deaths and injuries associated with the TAXUS and Express[2] stents. Id.

Plaintiff alleges that during July and early August 2004, defendants "continued to try to reassure the market about the safety of the Company's products through the issuance of public statements which were false and misleading." Id. ¶ 101. In particular, during a conference call with analysts on July 26, 2004, defendant Paul LaViolette responded to concerns about TAXUS by saying, "[Y]ou are dealing with simple lag time in the marketplace conversion of newer products, not necessarily a continuation of complaints from the new issue product." Id. At a meeting with a local hospital official on July 29, LaViolette stated that the company had "identified and fixed the problem." Id. On August 4, he stated that the problem was a "nuisance." Id.

On August 5, Boston Scientific announced that it was voluntarily recalling an additional 3,000 TAXUS stents.[3] Id. ¶ 102. The press release announcing the recall stated that it was prompted by the company's "ongoing monitoring" and noted that since the company had "modified its manufacturing process, implemented

[3] The complaint states the date of the third recall as August 4, but the press release announcing the recall is dated August 5.

new tracking software and introduced new inspection protocols," it had not had any confirmed non-deflation problems caused by focal neckdown in the units made with these changes in place. At this time, the company's stock price dropped another $2.41, or 6.6%. Id.

By the end of 2004, Boston Scientific had recalled 99,000 TAXUS and Express² stents because of manufacturing defects that plaintiff alleges had caused three deaths and dozens of serious injuries. Id. ¶ 103. The company spent over $57 million on these recalls. Id. ¶ 101. Between July 2, 2004, when the first recall was announced, and August 5, 2004, when the recall was expanded for a second time, the company's stock price dropped 21%. Id. ¶ 103.

Plaintiff's theory is that the investing world was aware of reports of patient death and injury involving TAXUS. However, defendants said that the problems with the TAXUS stents were caused by doctor unfamiliarity with the new product. It was natural for investors to conclude the problems would disappear over time as doctors became more familiar with the product, and there would be no recalls. Having given that explanation, the defendants, plaintiff argues, were required to disclose as soon as they could the connection between the patient problems, the manufacturing defect, and the manufacturing change remedying this problem.

B. District Court Opinion

In dismissing the TAXUS claims, the district court reasoned in a series of discrete steps.[4] It first noted that there was no violation in not disclosing the FDA major deficiency letter regarding TAXUS that Boston Scientific had received in September 2003, before the U.S. release of the product. Rather, the major deficiency letter was simply "a step in the FDA approval process which [Boston Scientific] had no duty to disclose." In re Boston Scientific, 490 F. Supp. 2d at 158; see also id. at 158 n.91 (citing 21 C.F.R. § 814.37(b) ("A major deficiency letter informs the applicant that its PMA [Premarket Approval Application] lacks significant information needed for FDA to complete the scientific review of, and render a final decision on, the PMA.")).

The court next turned to the adverse reports from doctors that defendants received prior to announcement of the recalls of the TAXUS and Express² stents in July and August of 2004. The court examined the company's statements that complaints received from American doctors in the spring of 2004 were comparable to complaints it had received the previous year from European doctors. Plaintiff asserted that these statements were false when made because the company knew that the problems in both Europe and the United States resulted from a product flaw rather than from the

[4] We discuss the district court's opinion only as it pertains to the TAXUS claims because only that part of the opinion is being appealed.

stated reason of doctor unfamiliarity with TAXUS. However, the district court concluded, plaintiff provided "little in the way of facts to support this claim. Lead Plaintiff pleads no facts to suggest that the complaints [Boston Scientific] received from American doctors were different than those it received from European doctors." Id. at 159.

With respect to the manufacturing change which Boston Scientific initiated prior to the U.S. launch of TAXUS, the court rejected plaintiff's allegations that this change was evidence that defendants knew TAXUS was defective and that the change was material information that should have been disclosed. Id. Here the district court invoked the doctrine of fraud by hindsight. The court reasoned that a manufacturing change does not necessarily mean that a product is defective or that a company knows that a product is defective since "[c]ompanies frequently adjust and change their products, and no rule requires a company to inform the public every time it modifies its manufacturing process." Id. The court pointed out that Boston Scientific's manufacturing change was conducted with the FDA's knowledge, at a time when the company had received only a limited number of complaints from European doctors, which had been tapering off. Id. at 160. Plaintiff did not contest that the manufacturing change was set in motion before TAXUS's release in the United States and would have been made regardless of whether the company received complaints from U.S.

doctors. Id. The district court further noted that "[t]he recalls were limited, and only applied to a fraction of the TAXUS stents released on the domestic market." Id. Thus, the court concluded, while "[i]n hindsight . . . it appears that this manufacturing change may indeed have been material," id. at 159, plaintiff failed "to allege facts that provide a strong inference that at the time of the manufacturing change, Defendants knew that TAXUS was defective or that the product would later be recalled," id. at 160.

With respect to defendant Paul LaViolette's July 29, 2004 remarks that Boston Scientific had identified and fixed the problem with TAXUS, the district court also invoked the doctrine of fraud by hindsight. A week after LaViolette's statements, the company initiated an additional recall of 3,000 TAXUS stents. However, the district court reasoned, there is no liability where "a plaintiff's claim rests on the assumption that the defendants 'must have known of the severity of their problems earlier because conditions became so bad later on.'" Id. (quoting In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 53 (D. Mass. 1998)). Here, the court concluded that plaintiff failed to allege facts giving rise to a strong inference that LaViolette knew at the time of his remarks that they were false or that an additional recall would be necessary. Id.

II.

On appeal, plaintiff argues that the district court erred in several respects. It argues that the court misapplied the doctrine of fraud by hindsight, resulting in the imposition of too stringent a pleading standard. More specifically, it claims that the court erroneously drew factual inferences against plaintiff regarding the manufacturing change and failed to account for the materiality of the change. Plaintiff further argues that the court misapplied the fraud by hindsight doctrine to LaViolette's remarks by discounting the temporal proximity between his statements and the third TAXUS recall, and it challenges the district court's factual assumption that the recall was limited in scope. Finally, plaintiff faults the district court for failing to consider the allegations of insider trading presented in the complaint. Overall, plaintiff argues the district court atomized the complaint and did not look at the overall pattern.

A. Pleading Requirements

We evaluate de novo whether a complaint meets the requirements of the PSLRA. ACA Fin., 512 F.3d at 58. As with any Rule 12(b)(6) motion to dismiss, we accept well-pled factual allegations in the complaint as true and make all reasonable inferences in plaintiff's favor. Id. The standard most recently articulated by the Supreme Court is that a complaint must allege "a plausible entitlement to relief" in order to withstand a motion to

dismiss under Rule 12(b)(6). Bell Atl. Corp. v. Twombly, ___ U.S. ___, 127 S. Ct. 1955, 1967-69 (2007); ACA Fin., 512 F.3d at 58.

A claim for securities fraud under section 10(b) and Rule 10b-5 must contain six elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. ACA Fin., 512 F.3d at 58 (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)). Only the first two elements are at issue in this appeal.

Information is material if a reasonable investor would have viewed it as "having significantly altered the total mix of information made available." Gross, 93 F.3d at 992 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 232 (1988)) (internal quotation marks omitted). The PSLRA provides that a misleading statement or omission is alleged when plaintiff claims that defendant made "an untrue statement of a material fact," 15 U.S.C. § 78u-4(b)(1)(A), or "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading," id. § 78u-4(b)(1)(B). "While a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead.'" Cabletron, 311 F.3d at 36 (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc)).

Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976); ACA Fin., 512 F.3d at 58. This circuit has held that a plaintiff can demonstrate scienter by showing that defendants either "consciously intended to defraud, or that they acted with a high degree of recklessness." Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002).

Securities fraud allegations also must meet the standards of Federal Rule of Civil Procedure 9(b)[5] and the PSLRA, which imposes heightened pleading requirements on private securities litigation. The PSLRA requires that when alleging that a defendant made a material misrepresentation or omission, a complaint must "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). If the allegation is "made on information and belief," then the complaint must "state with particularity all facts on which that belief is formed." Id.

With respect to scienter, the complaint must, "with respect to each act or omission . . ., state with particularity facts giving rise to a strong inference that the defendant acted

[5] Rule 9(b) requires that in alleging fraud or mistake, "a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In securities fraud cases, this requirement is comparable to and effectively subsumed by the requirements of the PSLRA. See ACA Fin., 512 F.3d at 58 n.7.

with the required state of mind." Id. § 78u-4(b)(2) (emphasis added). This requirement that plaintiffs plead facts giving rise to a strong inference of scienter differs from the general rule applied to other cases that a reasonable inference is sufficient to survive a Rule 12(b)(6) motion; in the PSLRA "Congress has effectively mandated a special standard for measuring whether allegations of scienter survive a motion to dismiss." Greebel, 194 F.3d at 195.

The Supreme Court's recent decision in Tellabs clarified that scienter should be evaluated with respect to "the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, 127 S. Ct. at 2509; see also ACA Fin., 512 F.3d at 58. "The inquiry . . . is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 127 S. Ct. at 2509. Tellabs also directed that courts consider "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged," id. at 2504, and held that a complaint survives when there are equally compelling inferences for and against scienter, id. at 2510; see also ACA Fin., 512 F.3d at 59.

B. Plaintiff's Allegations

We evaluate plaintiff's allegations in this context. In reviewing a motion to dismiss under Rule 12(b)(6), courts ordinarily will consider only documents attached to the complaint, but have made exceptions "for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; [and] for documents sufficiently referred to in the complaint." Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993).[6]

1. Manufacturing Change

Plaintiff alleges that defendants failed to disclose information about the manufacturing change prior to July 2, 2004, and this information was material. The primary motive alleged for the delay is that defendants wanted to build up inventory before announcing product recalls. Under the requirements of section

[6] We do not consider the transcripts of conference calls mentioned by both parties in their briefs and attached as an appendix to plaintiff's brief. In an order dated October 30, 2007, we rejected plaintiff's motion to expand the record before this court to include three transcripts that were not before the district court. We held that plaintiff had not demonstrated the "extraordinary circumstances" necessary to invoke this court's power to supplement a record under Federal Rule of Appellate Procedure 10(e)(2). United States v. Muriel-Cruz, 412 F.3d 9, 12 (1st Cir. 2005). We further held that although the complaint "contained some brief quotations from the documents, it did not expressly incorporate the entire documents, including the additional statements that [plaintiff] relies upon in its appellate brief." We also noted that regardless of whether the district court could have considered the transcripts if they were offered below, they had not been so offered.

10(b) and Rule 10b-5, plaintiff must demonstrate both that the defendants omitted material information and that they did so with the requisite scienter.

Securities actions raise questions of what corporate managers knew and when they knew it. These issues are pertinent both to materiality and to scienter. Moreover, something may be material because of other information or explanations that have been given by defendants. Thus plaintiff does not need to rely on a theory that there was an independent duty to disclose the manufacturing change. Further, we do not reach the district court's reasoning on the materiality, standing alone, of either manufacturing changes or the receipt of FDA major deficiency letters.

The existence of a material omission is usually a question for the trier of fact. See ACA Fin., 512 F.3d at 65 (citing Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 (1st Cir. 1996)). In this case, we cannot say that as a matter of law the complaint fails to raise a reasonable inference that this was a material omission.

The company's own statements draw a connection between the manufacturing change and the resolution of the balloon non-deflation problems, whether or not the earlier product had a defect. Indeed, Boston Scientific's Form 10-Q for the quarter ending June 30, 2004 included the following statements: "As a

result of its investigation, the Company has implemented reviews of its manufacturing process, additional inspections, and an FDA-approved modification to the manufacturing process for [TAXUS and Express² stents]. The Company believes these measures will be effective in reducing the occurrence of balloon non-deflation."

Because the manufacturing change, in combination with other changes, would have the effect of reducing balloon non-deflation, a jury could find that the company's continuing assertions that reported problems about TAXUS in the United States resulted from doctor unfamiliarity with the product rather than any defect in the product were misleading unless accompanied by disclosure of the manufacturing change and its connection to the balloon non-deflation problem. See Cabletron, 311 F.3d at 36. Among other things, the existence of this manufacturing change was pertinent to the issue of potential recalls, and it would raise the question whether, if there were continuing problems or recalls, the company would have on hand sufficient new products incorporating the manufacturing change in order to allow the company to replace the original TAXUS stents and maintain market share.

Assuming that a jury could find a material omission, the next requirement under section 10(b) and Rule 10b-5 is that defendants acted with the requisite scienter in not disclosing the manufacturing change sooner, i.e., prior to the first recall announced on July 2, 2004. Knowingly omitting material information

is probative, although not determinative, of scienter. Aldridge, 284 F.3d at 83 ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter."); see also ACA Fin., 512 F.3d at 65.

Plaintiff alleges that at some point prior to the FDA approval of TAXUS in March 2004, defendants knew that the problem with TAXUS was not doctor unfamiliarity but rather a manufacturing defect, and the company had already determined how to fix that defect. Specifically, plaintiff alleges that prior to the U.S. launch of TAXUS, defendants knew of adverse reports from doctors in Europe about balloon non-deflation, and that they also knew that the Express² metal stent, which used the same delivery system as TAXUS, had a "history of significant problems." CAC ¶ 93. Plaintiff also alleges that defendants received numerous adverse reports in the spring of 2004 from U.S. doctors, which they "minimized and misrepresented," and attributed to doctors' unfamiliarity with the new product. Id. Yet defendants proceeded with the U.S. launch of TAXUS and did not disclose this information until July 2, 2004.

Plaintiff alleges that defendants withheld this information to allow the company to build up its inventory of new, non-defective products which had been made with the manufacturing

change in place, in order to avoid loss of market share.[7] Plaintiff also alleges that several of the defendants engaged in insider trading during this lag period, benefitting from the delay.

Inferences supporting plaintiff's allegations about defendants' knowledge can be drawn from statements in Boston Scientific's Form 10-Q for the quarter ending June 30, 2004, filed on August 9, 2004. The Form 10-Q discusses the company's voluntary recall of the TAXUS Express² stent "due to characteristics in the delivery catheters that have the potential to impede balloon deflation during a coronary angioplasty procedure. Further analysis and investigation of the TAXUS Express² (paclitaxel-eluting) and Express² (bare metal) stent systems, both of which share the same delivery catheter, revealed that certain additional production lots exhibited these same characteristics." This statement acknowledges a connection between the balloon non-deflation problem and the characteristics of the delivery catheter. The statement also acknowledges that the company had been conducting ongoing analysis and investigation of the problem and as a result voluntarily expanded its recall on July 16. The statement goes on to say that the company would continue to work with the FDA to monitor the non-deflation problem.

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[7] Companies, of course, have other reasons not to have made an announcement from which some might have inferred there may have been a product defect causing injury and death, which could have been avoided by using different manufacturing techniques.

Tellingly, the statement also says that "[a]s a result of its investigation, the Company has implemented . . . an FDA-approved modification to the manufacturing process." (Emphasis added.) To the extent the company may be arguing that there was no connection between the manufacturing change and any characteristics of the catheter, defendants' own statements can be read to say that they implemented the manufacturing change in response to adverse reports, not independent of them.

Defendants made a similar statement in the press release announcing the July 16 expanded recall. After noting that the company had conducted "further analysis and investigation" that demonstrated the need for an expanded recall, the press release states: "The Company implemented review of its manufacturing process, additional inspections, and an FDA-approved modification to the manufacturing process for these products. The current and future production are not expected to experience similar balloon deflation problems."

Defendants make a different argument, addressed below, that even if the manufacturing change did solve the problem by preventing balloon non-deflation, that does not mean they knew the connection or were obliged to disclose it earlier.

Plaintiff gave a reason why defendants withheld information: so that they could build up an inventory of "new" TAXUS stents prior to announcing the recalls, thereby minimizing

supply disruptions and maximizing profit. In support of this theory is the fact that defendants asserted in their Form 10-Q for the quarter ending June 30, 2004 that they had been able to use their "existing supply of coronary stents not subject to the recall to replenish the U.S. market," although they also noted that they were unable to replenish the European market with existing stock and were hoping to do so during the third quarter of 2004. Similarly, in the press release announcing the July 16 recall, defendant James Tobin stated that, "We're fortunate that current TAXUS inventory levels will minimize service disruption in the United States, but we do expect some disruption internationally."

Plaintiff's proposed inferences are that defendants knew about the connection between adverse reports and the manufacturing change well before July 2, and withheld that information in order to build up inventory prior to announcing recalls. Under the PSLRA these inferences must be strong and must be weighed against competing ones. Defendants' inferences are that the manufacturing change was implemented for "innocuous" reasons not owing to any defect in the product, and that they did not know of a connection between the manufacturing change and the adverse reports they were receiving from U.S. doctors until the time of the first recall. Defendants' inferences are supported by the fact that balloon non-deflation complaints that defendants received from doctors in Europe in 2003 faded over time, indicating that such complaints

were in fact tied to doctor unfamiliarity. Additionally, defendants' press releases and Form 10-Q for the quarter ending June 30, 2004 stated that it was not the manufacturing change alone but rather this change in combination with others, including an improved inspection process, that would prevent non-deflation in the future. At no point did defendants communicate that the manufacturing change alone would fix the non-deflation problem.

Given these allegations, the district court held that plaintiff failed to plead facts providing a strong inference that at the time of the manufacturing change, defendants had the requisite scienter. In re Boston Scientific, 490 F. Supp. 2d at 160. It reasoned that the manufacturing change was implemented with the FDA's knowledge and approval, at a time when the company had received only a "limited number of complaints from Europe which had tapered off after the product's release." Id. Moreover, defendants asserted and plaintiff did not dispute that the manufacturing change would have been put into place regardless of whether the company received complaints from doctors in the United States. Id. The district court did not address the key question of inferences about whether defendants knew that the manufacturing change was related to non-deflation complaints at some point prior

to the July 2 recall, not just when they first initiated the change.[8]

The district court did not have the benefit of the Tellabs opinion, which reversed a higher standard for scienter imposed by the prior law of this circuit. We apply Tellabs and that leads us to a different result. While there is support for defendants' inferences, we think, at this stage, that plaintiff's inferences are at least equally strong. First, there is a very reasonable inference that defendants initiated the manufacturing change as a result of non-deflation complaints it had received from Europe, even if these complaints had tapered off over time.

Other inferences may be drawn favorable to plaintiff by proper recognition of the limits of the doctrine of fraud by hindsight. Fraud by hindsight refers to allegations that assert no more than that because something eventually went wrong, defendants must have known about the problem earlier. "[A] plaintiff may not simply contrast a defendant's past optimism with less favorable actual results, and then 'contend[] that the difference must be

[8] Plaintiff and defendants dispute the extent of the recall, with plaintiff arguing that all pre-manufacturing change stents were recalled and defendants responding that approximately 445,000 "old" TAXUS stents had already been shipped and implanted and therefore were not problematic or recalled. We need not resolve this factual question at this point because the extent of the recall is largely irrelevant to our analysis. There seems not to be a dispute that a connection existed between the manufacturing change and the non-deflation problem that necessitated the recall.

attributable to fraud.'" Shaw, 82 F.3d at 1223 (quoting DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990)).

The doctrine has been applied in a number of different situations. We recognize that the effect of use of the doctrine at the Rule 12(b)(6) dismissal stage is to cut off the case as a matter of law, without further factual development. As some commentators have stated, "[A]t this stage, a court must be cautious. The case has not yet developed. In cutting off the case on the pleadings by citing hindsight, the court is essentially making a prediction that the discovery process will yield only evidence that requires the benefit of the hindsight bias to seem adequate [to support the allegations]." M. Gulati, J. Rachlinski & D. Langevoort, Fraud by Hindsight, 98 Nw. L. Rev. 773, 787 (2004). Meanwhile, at the pleadings stage, "a bad outcome truly is relevant to the likelihood of fraud." Id. at 815. Indeed, this court has held that "in determining the adequacy of a complaint . . . we cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence." Shaw, 82 F.3d at 1225. The law "proscribes the pleading of 'fraud by hindsight,' but neither can plaintiffs be expected to plead fraud with complete insight." Id. (quoting Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.)).

In Shaw, we held that the doctrine did not apply when plaintiffs provided "a series of factual allegations relating to a

combination of developments known to the company . . . that could have provided a basis for advance knowledge of the information" which was eventually disclosed. Id. at 1224. We held that these allegations of developments known to the company, along with (admittedly weak) evidence of insider trading and the temporal proximity between the date of the alleged omission and the eventual disclosure (less than a month), were sufficient to survive a motion to dismiss.[9] Id. at 1225.

Defendants in this case urged, and the district court accepted, that plaintiff's allegations amounted to nothing more than an allegation of fraud by hindsight: that simply because the manufacturing change eventually was linked as a remedy for the balloon non-deflation problem, defendants must have known about the connection earlier. This approach fails to consider the other allegations that plaintiff made from supporting documents. For instance, there is no dispute that the manufacturing change related to the laser welding of the delivery catheter and balloon, and it may be inferred this addressed the same problem which resulted in the recalls. It is also clear that defendants had received non-deflation reports from doctors in Europe before instituting the manufacturing change, as well as numerous non-deflation complaints from U.S. doctors while the company was in the process of

[9] Shaw was decided before the PSLRA was enacted, but Rule 9(b)'s particularity requirement is similar to the requirements of the PSLRA. See supra n.5.

implementing the change. Moreover, defendants' own SEC filings and press releases reveal that they reassured the public that they had implemented the manufacturing change in response to complaints of non-deflation, so that the "new" TAXUS would not suffer from the same problems. The company said it had been monitoring, analyzing, and investigating the problem and appropriate responses. It is fair to infer the company has highly effective information systems. Cf. id. at 1224 n.38. Defendants are in a highly regulated industry and the company, it can be inferred, constantly monitors reports of patient injury and death and looks for prompt solutions to such problems.

This is not the classic fraud by hindsight case where a plaintiff alleges that the fact that something turned out badly must mean defendant knew earlier that it would turn out badly. Denny, 576 F.2d at 470. Nor is this a case where there is no contemporaneous evidence at all that defendants knew earlier what they chose not to disclose until later. DiLeo, 901 F.2d at 626-7.

2. LaViolette's Statements

Plaintiff also disputes the district court's rejection of the LaViolette allegations under the doctrine of fraud by hindsight. The allegations are that defendant Paul LaViolette made public statements that were "false and misleading" and constituted a "misrepresentation" (1) when he stated on July 29 -- a week before the third recall was announced on August 5 -- that the

problem with TAXUS had been "fixed," and (2) when he stated on July 26 that there was simply a "lag time" in the marketplace's conversion to the improved version of TAXUS. CAC ¶ 101.

Plaintiff's complaint may be read as alleging a material omission and as supporting scienter. LaViolette's remarks were misleading not because the problem had not been "fixed," but because LaViolette excluded any mention of the upcoming recall. In other words, it was misleading for LaViolette to say that the problem had been "fixed" while failing to mention that a third recall, of another 3,000 stents, would be announced a week later.

As with plaintiff's allegations regarding the manufacturing change, we cannot say that LaViolette's omission was immaterial as a matter of law. The investors with whom LaViolette was speaking in the conference call would very well have wanted to know about the existence of an upcoming recall in addition to hearing LaViolette's assurances that the TAXUS problems were in the past.

With respect to scienter, the district court held that plaintiff was merely alleging fraud by hindsight because plaintiff was claiming no more than that LaViolette should have known about the recall earlier. According to the district court, "Lead Plaintiff fails to allege facts that provide a strong inference that Defendant LaViolette knew that an additional recall was

necessary or that his remarks were false when he made them." In re Boston Scientific, 490 F. Supp. 2d at 160. We disagree.

This fails to account for the very short amount of time between LaViolette's remarks, some of which were made on Thursday, July 29, and the third recall, which was announced the following Thursday, August 5. Temporal proximity alone is insufficient to establish a claim for fraud, see Shaw, 82 F.3d at 1225, but this court has insisted on a "fact-specific inquiry" regarding scienter. Greebel, 194 F.3d at 196. The extremely short time period here is strong evidence.

Moreover, LaViolette was the company's Chief Operating Officer and a point person on TAXUS, and so he would presumably have been aware of the status of the company's "ongoing monitoring" of "old" TAXUS stents. CAC ¶¶ 18, 93. The third recall, like the two before it, was voluntary and initiated by Boston Scientific rather than the FDA.

3. Insider Trading

Because the district court dismissed on scienter grounds, it did not consider the insider trading allegations. We do consider these allegations in the overall mix.

Insider trading cannot establish scienter on its own, but it can be used to do so in combination with other evidence. Greebel, 194 F.3d at 197-98; Shaw, 82 F.3d at 1224. Insider trading in suspicious amounts or at suspicious times may be

probative of scienter. Greebel, 194 F.3d at 197; Greenstone v. Cambex Corp., 975 F.2d 22, 26 (1st Cir. 1992). Plaintiff alleges that all defendants engaged in insider trading during the narrowed class period of December 3, 2003 to August 5, 2004, see CAC ¶¶ 15-23, and they argue that stock sales of $40.82 million by James R. Tobin, $54.2 million by Lawrence C. Best, $4.2 million by Fredericus A. Colen, and $3.3 million by Robert G. MacLean within the two months following the FDA's approval of TAXUS are particularly suspicious, see id. ¶ 96.

However, we acknowledge that plaintiff's complaint has allegations going the other way. Plaintiff alleges that all but one (Tobin) of these defendants engaged in insider trading at periods outside of the narrowed class period, including some after the recalls were announced and the manufacturing change was disclosed. This undermines the inference that the timing of the trading was suspicious. Id. ¶¶ 15-23. Plaintiff also does not allege that the particular timing of the trading was suspicious other than that it occurred during the eight-month period to which the appeal is limited: the trading has not been linked, for instance, to defendants' non-disclosed knowledge of the manufacturing change or problems with TAXUS.

Defendants respond that many of these stock sales, including all of Best's and many of Tobin's, were effectuated pursuant to Rule 10b5-1 trading plans that removed control of the

sales from the individual defendants. It was defendants' choice to move to dismiss the case on the pleadings without presenting evidence. As a result, there is no evidence of when the trading plans went into effect, that such trading plans removed entirely from defendants' discretion the question of when sales would occur, or that they were unable to amend these trading plans.

The insider trading claims as alleged are on the weaker end of the spectrum. But, as in Shaw, "we think that the plaintiffs' allegations of insider trading, inasmuch as they are at least consistent with their theory of fraud, provide some support against the defendants' motion to dismiss." 82 F.3d at 1224; see also Greebel, 194 F.3d at 197-98 ("The vitality of the inference to be drawn depends on the facts, and can range from marginal to strong." (citations omitted)).

Plaintiff has alleged a significant amount of insider trading in the months before the announcement of recalls in July, which caused the stock price to drop. CAC ¶¶ 100, 102. The company's stock price was at an all-time high in the months before the recalls were announced, often closing above $40. Id. ¶¶ 15-23, 96, 100. It fits with plaintiff's theory that defendants would have sold stock at this time, knowing that the price would drop when the manufacturing change, acknowledging a defect, was announced. If defendants were unaware of the connection between the non-deflation reports they were receiving and the manufacturing

change, a fact finder could reasonably ask why they would have sold so much stock at a time when the company appeared to be soaring on the strength of TAXUS.

Given plaintiff's specific factual allegations, the temporal proximity between LaViolette's statements and the third recall, and the alleged insider trading, we think that plaintiff has pled enough to give rise to inferences that are at least as strong as any competing inferences regarding scienter.

C. Group Pleading

Defendants argue that plaintiff has engaged in impermissible group pleading and that several of the defendants should be dismissed from the case now that the subject area has been narrowed on appeal because they are not specifically alleged to have been involved with TAXUS.[10] The district court did not address the issue. We decline to address the issue in the first instance.

We take into account, as in Cabletron, the fact that the overall complaint survives, the pre-discovery posture of the case, and the fact that all of the individual defendants held positions

[10] Under the group pleading presumption, a court may attribute all statements to the defendants as collective actions without considering the liability of each individual defendant. This court has recognized "a very limited version of the group pleading doctrine for securities fraud." Cabletron, 311 F.3d at 40. There has been "great debate about the doctrine's continued existence after enactment of the PSLRA," a question on which this circuit has not taken a position. Id. We need not here resolve whether group pleading survives the PSLRA.

of significant responsibility within the company and therefore potentially face control person liability under section 20(a). Cabletron, 311 F.3d at 41. We think the questions should be resolved in the first instance by the district court.

D. Section 20(a) Liability

Plaintiff has also made allegations against defendants under section 20(a), which establishes liability for any person who "directly or indirectly[] controls any person liable" for a violation of securities laws. 15 U.S.C. § 78t(a). The district court summarily dismissed the section 20(a) claims on account of its dismissal of the section 10(b) claims. Reinstatement of section 20(a) claims is generally appropriate when section 10(b) claims have been reinstated and the section 20(a) claims had been dismissed by the district court because of its dismissal of the section 10(b) claims. Cabletron, 311 F.3d at 41; see also Nathenson v. Zonagen Inc., 267 F.3d 400, 426 n.29 (5th Cir. 2001); Hollin v. Scholastic Corp. (In re Scholastic Corp. Sec. Litig.), 252 F.3d 63, 77-78 (2d Cir. 2001).

On appeal, defendants claim that plaintiff has failed to allege facts demonstrating that any of the individual defendants are subject to control person liability and therefore the section 20(a) claims should be dismissed even if the section 10(b) claims are allowed to stand. We disagree. "Control is a question of fact that 'will not ordinarily be resolved summarily at the pleading

stage.' The issue raises a number of complexities that should not be resolved on such an underdeveloped record." Cabletron, 311 F.3d at 41 (citation omitted) (quoting 2 T.L. Hazen, Treatise on the Law of Securities Regulation § 12.24(1) (4th ed. 2002)). The practical effect of reinstating the section 20(a) claims is small since the same defendants are involved as with the section 10(b) claims, and individual defendants are not foreclosed from challenging their liability under section 20(a) in the future. Id. at 41-42.

III.

We do not address the other requirements of section 10(b) and Rule 10b-5, which were not raised in this appeal by either party.

We reverse the dismissal and remand the case to the district court for further proceedings consistent with this opinion.