United States Court of Appeals
For the First Circuit

No. 10-1663

MISSISSIPPI PUBLIC EMPLOYEES' RETIREMENT SYSTEM,

Plaintiff, Appellant,

JACK YOPP, Individually and on Behalf of All Others Similarly Situated, ET AL.,

Plaintiffs,

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. Douglas P. Woodlock, U.S. District Judge]

Before

Lynch, Chief Judge.
Boudin and Thompson, Circuit Judges.

Carolyn G. Anderson, with whom Anne T. Regan, Patricia A. Bloodgood, Zimmerman Reed, PLLP, David S. Nalven, Hagens Berman Sobol Shapiro, LLP, Richard A. Lockridge, Gregg M. Fishbein, Nathan D. Prosser, Lockridge Grindal Nauen, PLLP, James E. O'Neil, Law Offices of James E. O'Neil, Mike Moore, and Moore Law Firm were on brief, for appellant.

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

August 4, 2011

LYNCH, Chief Judge. In this securities class action, plaintiff Mississippi Public Employees' Retirement System alleges that senior management of Boston Scientific Corporation (BSC), a publicly traded manufacturer of medical devices in which plaintiff invested, withheld material information and made misleading statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Securities Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5.

In an earlier opinion, we reversed a Rule 12(b)(6) dismissal of plaintiff's complaint, finding that the inference of scienter advanced by the plaintiff was at least as cogent and compelling as the contrary inference, satisfying the "strong inference" pleading standard of the Private Securities Litigation Reform Act. See Miss. Pub. Emps. Ret. Sys. v. Boston Scientific Corp. (BSC I), 523 F.3d 75 (1st Cir. 2008). After the district court permitted discovery, the defendants filed a motion for summary judgment, testing whether the evidence, and not merely the allegations, withstood scrutiny. The district court found that the evidence did not and granted defendants' motion. See In re Boston Sci. Corp. Sec. Litig., 708 F. Supp. 2d 110 (D. Mass. 2010). The plaintiff appealed, and as is common in litigation, the shape of the case has changed since we last reviewed it.

Plaintiff's central claim is that defendants were aware that BSC would likely need to implement a significant recall of its

TAXUS Express[2] Paclitaxel-Eluting Coronary Stent System ("Taxus"), and that through affirmative statements and omissions, defendants intentionally or recklessly misled the investing public about the existence, cause, and degree of this risk. As to omissions, plaintiff argues that starting in November 2003, defendants chose not to disclose or implement a manufacturing solution to a "no-deflate" problem with Taxus because doing so would have caused a delay in the FDA's approval of the device. This, in turn, would have hampered BSC's business strategy of building up sufficient Taxus inventory to flood the market upon its launch. As to affirmative statements, plaintiff claims that defendants "lulled" the market by repeatedly saying that the problems were due to doctor inexperience with the stent system, rather than manufacturing, and that recalls were unlikely.

The district court found that on the undisputed facts, drawing all inferences in plaintiff's favor, no reasonable jury could find sufficient evidence of three key elements of securities fraud.[1] We affirm on the sole ground that plaintiff has failed to

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[1] First, it held that the evidence regarding defendants' statements, omissions, and stock sales did not support a reasonable inference that they acted with scienter in not disclosing or implementing the manufacturing fix or recalls sooner, and that rather than lulling the market, defendants had made a reasonable effort to address the risks inherent in the launch of Taxus. Second, the court held that no reasonable jury could find that any of the alleged misrepresentations by the defendants were material because the market had available sufficient corrective information to cure any arguably misleading statements or omissions. Third, the court held that in light of the timing of BSC's disclosures

produce evidence that would permit a reasonable inference that defendants acted with scienter.

I.

We assume some familiarity with our prior opinion and focus on the facts and claims that are key to this appeal.

A. Stent Systems

In treating coronary artery disease (i.e., clogged arteries), physicians often use stents in angioplasty procedures as an alternative to open heart surgery. A stent delivery system consists of three central components: (1) a catheter, which is a long hollow plastic tube used to guide the stent along the inside of the arteries, (2) a balloon that is laser welded to the end of the catheter, and (3) the stent itself, which is "crimped" (or collapsed) on the deflated balloon. During an implant procedure, the balloon is inflated, which expands and deploys the stent and clears the blockage. After the stent is deployed and apposed to the artery wall, the balloon is deflated and withdrawn.

BSC makes two different stent systems. There is the Taxus system, on which plaintiff's claims rest, and the Express[2] system, which is very similar to Taxus. The primary difference between them is that the stent in the Taxus system is coated with a polymer containing a drug to ease complications associated with

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regarding the no-deflate complaints and its manufacturing solution, there was insufficient evidence to support plaintiff's claim that the alleged misrepresentations caused plaintiff's economic losses.

stent implant, while the stent in the Express^2 system is not coated. Both the Express^2 and Taxus systems are built using the same Express^2 catheter.

B. The Express^2 System

We begin with an overview of the Express^2 system and BSC's gradual improvement of it, as this background is necessary to understand the nature and basis of the plaintiff's claims about Taxus. BSC's improvements to the Express^2 system can be categorized into three phases on the undisputed evidence.

1. Express^2 Phase One: Reducing Process Variability

BSC began selling the Express^2 system outside the United States in June 2001, and received FDA approval for U.S. sales in September 2002. The system was manufactured at company facilities in Maple Grove, Minnesota, and Galway, Ireland.

In early 2003, BSC received 11 reports of complaints that the balloon on Express^2 devices had not deflated, including 3 from the same manufacturing lot. While BSC had received occasional complaints of this problem since the product's launch, the increased rate and the existence of multiple no-deflates from the same batch caused BSC to conduct an inquiry. Multiple-complaint lots meant that the problem was not dispersed throughout all devices, and consequently that the normal method of calculating frequency did not apply.

BSC initiated a Site Level Correction Action (SLCA) at Maple Grove led by Paul Weiss, and a corresponding Corrective and Preventative Action (CAPA) at Galway led by Niamh O'Byrne. SLCA and CAPA investigations are commenced to investigate issues that are systemic or could disrupt business operations. As part of their investigations, Paul Weiss and Niamh O'Byrne opened a Product Inquiry Report (PIR). A PIR is used to investigate and make recommendations for in-house actions or field actions to BSC's Field Action Committee (FAC), which has ultimate responsibility for instituting field actions such as recalls. Although the multiple-batch no-deflate complaints were about Express[2], Taxus (which was only being sold outside the United States at the time) was included in the PIR because both systems were built using the same Express[2] catheter.

On May 15, 2003, the PIR team issued a report on the primary cause of the no-deflate problem. The team found that the problem was due to a condition known as "focal necking" or "focal neckdown," where the "distal outer" (the portion of the catheter that is welded to the balloon) becomes elongated or stretched, preventing the withdrawal of the fluid used to inflate the balloon. The team further found that this focal necking had two primary causes: (1) excessive heat at the laser bond of the balloon and the distal outer, which could be caused by a laser that was too hot or misaligned, and (2) a subsequent excessive tensile force exerted in

the area of the bond, which could occur either during or after manufacturing.

While the team could not identify the specific cause of the tensile force, it was able to identify several in-house actions to prevent or lessen the incidence of focal necking. To address issues with the laser weld, it recommended reducing the laser energy settings, increasing the magnification of the alignment camera, and retraining operators. For the same reason, the team also recommended using only distal outers manufactured in Maple Grove, which were found to be more robust than those manufactured in Galway, and launching an investigation to understand why the Galway distal outers appeared more prone to focal necking.

The PIR team also reported on the frequency of the no-deflate issue. For Express[2] devices manufactured in Galway, it found twenty no-deflates out of over 260,000 revenue shipments, with two lots producing three complaints each; for those manufactured in Maple Grove, it found only one no-deflate.[2] For Taxus devices, which were only manufactured in Galway at the time, it found zero no-deflates out of over 31,000 revenue shipments. Given this "low rate of occurrence combined with the limited severity in all but one case," the PIR team concluded that "[n]o field action is recommended at this time."

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[2] A May 23 update reported twenty-one, rather than twenty, no-deflates on Galway Express[2] devices, accounting for a complaint that was reported on May 16.

The team was asked at a May 22 meeting to determine the scope of the no-deflate issue in case a recall was needed, and it found no factors that could be used to identify some devices as being higher-risk. It considered data on numerous parameters of the focally necked devices--including laser weld, elongation, type of resin used, and extrusions--but found no correlations from which to scope the problem. On May 23, the team issued a PIR with the same conclusions and recommendations that it had reached in the May 15 report.

On May 27, the FAC accepted the PIR team's recommendations and conclusions. It agreed that a recall was not warranted at the time, finding that "the product in the field was within all of its established specifications, the frequency of issues reported [from] the field were extremely low, and the consequences, while potentially severe in some cases are not outside those expected with this type of procedure." The Chairman of the FAC, Paul Sandman, later testified that the FAC did not institute a recall because "there weren't any factors that indicated that these failures were caused by a manufacturing problem."

The FAC also directed that the PIR be "clarified to state that the issue involves units within specification, and indistinguishable from a visual standpoint, being subjected in the field to a level of tensile force exceeding that for which the

product was designed." It is unclear whether this was meant to supplement, or replace, the PIR's statement that the tensile event may have also occurred during manufacturing.[3]

In implementing the PIR team's suggestions, BSC sought to harmonize the robustness of the stent systems produced at Galway with those produced at Maple Grove. The changes focused on the properties of the distal outers and the proximal welding process. As to the proximal welding process, BSC increased the magnification used to line up the stent system components, making it identical with that in Maple Grove, and retrained the Galway operators on the proper alignment of the laser weld and the proper handling of the catheters to avoid tensile forces on the product. These changes were implemented in May. As to the quality of the distal outers, Galway immediately switched to using Maple Grove distal outers in its production,[4] and over the following three months, BSC implemented various changes to harmonize the manufacturing of distal outers at the facilities, including aligning their elongation testing equipment, extrusion parameters, and distal outer measurement methods. BSC also introduced changes to ensure

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[3] The FAC also directed that it be provided with bi-weekly updates regarding no-deflates and the effectiveness of the preventative actions recommended in the PIR. In addition, the PIR team updated its analysis on June 10, July 10, and October 17, 2003, each time concluding that no field action was warranted.

[4] Eventually, in December 2003, Galway resumed manufacturing its own distal outers.

that the area of the proximal weld was not exposed to excessive heat during laser welding, including implementing an in-process manufacturing acceptance criterion for the length of the weld (the "Matte Finish Length").[5]

Because none of these changes affected device design or performance specification, BSC determined that prior FDA approval was not required, and implemented them in accordance with its standard BSC Quality System procedures.

2. Express[2] Phase Two: A New Design Specification

Although BSC determined that a recall was not necessary, it nevertheless decided to further investigate the no-deflate issue. Internal correspondence from this period shows that the no-deflate issue was seen by some in the company as "urgent" and a "severe compliance risk." So in Galway, a "six sigma" team was initiated on May 28, 2003 to investigate the cause of focal necking.[6] In addition, following up on the CAPA investigation's finding that the material properties of the distal outer shaft could contribute to the robustness of the proximal balloon weld, BSC created a team in Maple Grove--where the distal outer shafts

[5] A weld length that is too long indicates that the device might have been produced with excessive laser heat, thinning the distal outer and making it more prone to focal necking.

[6] Six sigma is an engineering problem-solving methodology that employs mathematics and statistical tools to refine and improve industrial processes.

had been found to be more robust--to develop a new design specification for the distal outer.

Over the next four months, the Maple Grove team developed a proposal that focused on the elongation properties of the distal outer. Elongation served as an "indirect measure of the molecular orientation and crystallinity of the polymer material" used in the distal outer. By setting a length that the distal outer could be stretched before breaking, BSC aimed to ensure that each of its distal outers had material properties that would "increase its robustness to subsequent thermal processing that occurs when the outer is laser welded to the balloon component of the delivery system."

On October 3, 2003, BSC filed a supplement to its Express[2] Premarket Approval (PMA) with the FDA, seeking permission to implement "a test method to evaluate the elongation property of the extruded distal outer shaft component for the Express[2]." In this document, BSC stated that the change was meant to address no-deflate complaints. BSC disclosed that it had "received a small number of field complaints (approximately 0.0148% complaint rate) regarding the delivery system balloon's failure to deflate" and provided a table listing the no-deflates by month and manufacturing site for January through August 2003. It explained that although it had been unable "to definitively confirm the root cause of the failure," its investigation had determined that "at least part of

the root cause is due to inconsistent material properties of the distal outer shaft component," and that the new design specification was intended "(1) to improve the robustness of the distal outer shaft, and (2) to improve the consistency between distal outer shafts manufactured at BSC's [Maple Grove and Galway] facilities."

Finally, BSC notified the FDA in this supplement of all of the May 2003 corrective actions that it had taken, explaining its determination that these changes did not require FDA approval. It also reported on the success of these measures, noting that the fifteen no-deflate complaints for Express[2] devices that it had received between May and August 2003 were for devices built prior to the implementation of the changes.

The FDA approved BSC's request on October 24, 2003.

3. Express[2] Phase Three: Reticle Inspection and Laser Shift

At the same time that BSC was implementing the elongation specification, the six sigma team was completing its report on the laser shift. It found that by shifting the location of the laser used to bond the balloon to the distal outer, from .4 mm to .8 mm, focal necking would be prevented, "regardless of the settings of the other factors."[7] However, as Peter Delmer, who headed the

[7] An earlier company investigation, completed in November 2002, had identified a laser shift of .1 mm to .2 mm as one partial solution, among several others, to the problem of focal necking. However, the report stated that not all of recommendations needed

effort in Galway, stated, "an awful lot more work would have to be done in order to implement that solution." The company needed to verify that the change would not introduce new problems and also confirm whether .8 mm was the ideal position, or whether .7 mm would be better.

This validation work was assigned to Kevin Griffin, a Process Development Engineer at Maple Grove. On September 2, Griffin created a plan estimating that a proposal could be submitted to the FDA in November. However, he stated even at this time that the plan was "a bit optimistic."[8] His team was advised to keep those working on Taxus, a different group, informed because any manufacturing change submitted to the FDA would need to be assessed for its "impact to the Taxus PMA." In the following months, the team worked to develop a validation protocol, which involved discussions with various branches of the company, including manufacturing and regulatory.

At this point, as of the beginning of the Class Period in November, there had been only two no-deflate complaints for the

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to be implemented to prevent focal necking, concluding that "laser dwell time has the greatest effect" and that "reducing the energy applied to the bond site will have the most pronounced effect in producing bonds more robust to focal necking." To "reduce the chance of a 'hot' weld," the report recommended changes to the Matte Finish Length criteria. Such changes were implemented in the spring of 2003.

[8] Griffin circulated another draft of the validation plan on December 3, and another revised version on February 5. The research was not completed until the spring.

tens of thousands of Express[2] and Taxus devices manufactured at Galway after the introduction of the May 2003 changes, and there had been only three no-deflates ever on Express[2] devices manufactured at Maple Grove. Consequently, Paul Weiss, the leader of the no-deflate PIR, concluded on November 26, 2003 that "the interim actions have been very effective."

C. The Taxus System

During this time period, BSC was also working to have Taxus approved for sale in the United States, after having distributed it outside the United States since February 2003. It established a "Taxus PMA Council," which oversaw the filing of five separate modules to the FDA between February and June 2003 and continued to meet throughout the summer to monitor the PMA progress and amendments.

On October 7, 2003, the Taxus PMA Council decided that no additional manufacturing changes to the Taxus PMA would be submitted after October 31 unless they were considered "critical" and approved by the Council, as these changes could jeopardize the FDA's review of the Taxus PMA. The Taxus Council was aware that a separate team of engineers was also working on a laser shift for the Express[2] catheter, but did not consider the laser shift to be "critical." Paul Weiss testified that "the evidence at that time was we had corrected the issue" and that the laser shift was merely

seen as "a preventive action to make the product more robust to focal necking."

On November 20, 2003, the first day of the Class Period, a company press release announced that the FDA's circulatory devices panel would recommend that Taxus be approved for sale in the United States. BSC ramped up Taxus production in anticipation for the U.S. launch.

It is important to note that the units being manufactured for the U.S. launch incorporated the October 2003 distal outer elongation specification, as well as a new manufacturing process known as "cone puffing," which had not been used on the units produced for sale outside the United States. Cone puffing involves inflating one cone of the balloon so that it goes over one end of the stent. This technique was implemented to better secure the stent's placement on the device, preventing the stent from becoming dislodged during implantation. There is no evidence that anyone at this point suspected or had reason to suspect that cone puffing could contribute to focal necking.

In the following months, research on validating the laser shift continued. A December 24, 2003 memo from Kevin Griffin reported that although the team had "learned a lot about what affects focal necking, there is still uncertainty due to test method repeatability, other known contributors (like heat shrink) that are not well understood yet, and the underlying polymer

science is still being investigated." He stated that on an "aggressive" research time frame, validation could be completed by February 20, 2004.

On March 4, 2004, the FDA approved Taxus for sale in the United States, and within the first couple of weeks following the U.S. launch, Boston Scientific received about a dozen no-deflate complaints on Taxus (but not Express[2]) units manufactured in Galway and in Maple Grove. This included multiple complaints for two Taxus manufacturing lots. BSC initiated a "Worldwide Focal Necking Operations Team" to investigate the failures and determine whether any lots had a higher propensity to focally neck.

While the team was ultimately unable to identify any such lots, the co-chair of this team issued a memo on March 23 suggesting that BSC add a criterion for the minimum outer diameter ("minOD") of the distal outer at the location of the laser weld to eliminate the subjective nature of prior visual inspections, and add an in-process inspection to measure the minOD to ensure that it met the criterion. The memo also noted that based on simulations with surgeons, it appeared that surgeons were not exerting the degree of tensile force on the devices that would be necessary to cause the necking. It concluded: "We don't know where in our processing the tensile forces are occurring to cause the focal neck . . . . The loading of the balloon protector after folding and

after cone puffing has been highly suspected, but we have not been able to draw [a] direct correlation to focal necking."

Two days later, on March 25, BSC received notice that one hospital in which a no-deflate had required surgical removal of the stent decided to cease using Taxus at all of its facilities until it had determined whether this was an isolated incident or a product defect.

At the end of March, the design, testing, and validation work on the laser shift for both Express[2] and Taxus was completed. On April 2, 2004, BSC submitted a Special PMA Supplement to the FDA for its Taxus and Express[2] systems. BSC requested permission to (1) shift the laser so that it was .8 mm, instead of .4 mm, from the edge of the overlap between the balloon and the distal outer; (2) add a criterion for the "minOD" of the distal outer at the location of the laser weld to eliminate the subjective nature of prior visual inspections; and (3) add an in-process inspection to measure the minOD to ensure that it met the criterion.

As the minOD was determined to be important independent of the laser shift, BSC also added a "reticle inspection" to measure the minOD, which did not require FDA approval and was implemented on April 28-29. The reticle inspection involved a magnification tool with guidelines to assist in measuring the bond width, because bonds of a certain minimum width were found to be

robust against focal necking regardless of the location of the laser.

On April 16, 2004, the FDA contacted BSC to schedule a teleconference and to express concern regarding a type of complaint regarding Taxus that BSC had not yet addressed to the FDA in any of its PMA filings. The FDA had received a number of reports in which the balloon deflated but was difficult to remove, in some cases because the balloon was stuck to the distal end of the stent.

This issue, known as "sticky stent," was different from the no-deflate problem and was caused by the fact that the Taxus stent, unlike the Express[2] stent, was coated with a polymer containing a drug that could make the balloon feel stuck to the stent. BSC had became aware of this issue in 2003, when it launched Taxus outside of the United States and received many complaints about it. During the months following the launch outside the United States, BSC found that the complaints about this issue subsided as physicians became familiar with the sticky feel of the polymer-coated stent and learned, through BSC training and experience, how to work with it.

During BSC's first quarter analyst conference call on April 20, 2004, Paul LaViolette, Senior Vice President at BSC, was asked about the sticky stent issue. An analyst with Bank of America Securities asked if LaViolette had "any thoughts on why we are hearing this occur in the U.S., while over the last 12 months

we didn't hear much about this occurring in Europe." LaViolette replied that BSC had received similar complaints internationally when Taxus launched in 2003, but that once physicians became accustomed to using Taxus, "essentially all complaint activity subsided." He said that "if you look at international utilization today, and if you look at complaints for any kind of removal difficulty, there are virtually no ongoing complaints," and that this "confirms for us what we understand about this particular issue, which is that there are some things to get used to." He also stated that were "no discussions related to any kind of field action."

On April 24, the Boston Globe reported that BSC had received 27 reports of difficulty implanting Taxus stents. The article differentiated between the sticky stent and no-deflate problems, reporting: "A Boston Scientific spokesman said that in most of the reported cases the balloons . . . seemed to stick to the coating of the stent, creating a potential blockage. In about six of the cases the balloon wouldn't deflate, or would only deflate slowly." It also reported:

> Boston Scientific spokesman Paul Donovan said the number of problem cases was minor relative to the 84,000 Taxus stents implanted in American patients since the FDA approved the device March 4. He said a few doctors in Europe reported similar problems when Taxus was initially approved for use there last year, but the complaints ended as doctors became more comfortable with the stents.

On April 26, 2004, The Wall Street Journal also reported on these 27 reports of difficulties with Taxus:

> Boston Scientific said it has received 27 reports of difficulties removing or deflating the balloon used in the angioplasty. But it knows of no deaths or complications due to the issue. It adds that it believes the problem will disappear once physicians gain experience using the Taxus.
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> "This sort of thing does tend to happen as physicians gain experience with the device," said company Senior Vice President Paul LaViolette.

The article also reported that "[c]opies of 21 of these reports reviewed by The Wall Street Journal showed that most of the complaints appeared to be minor annoyances, requiring the doctor to fiddle a bit to remove or deflate the balloon."

On April 27, 2004, Goldman Sachs released a report reiterating its buy rating for BSC, explaining that it had "conducted a review of the most recently available adverse event reports (MDR's) for the Taxus stent in the FDA database" and "conclude[d] that the nature of the adverse events is within the scope of what can be expected in the early stages of a new interventional product launch." It reported that "the current rate of adverse events on a worldwide basis is extremely rare at 0.01% or 11.8 per 100,000 cases" and explained that although "there is a tendency for under-reporting of events . . . we believe that the event rate is so low that even with under-reporting there is no significant issue." The report stated that Goldman Sachs had been

in "extensive conversations" with BSC management, and that management was "consistent in its stance that the performance reports are far and few between, and not unexpected in the early stages of a broad US launch."

In the meantime, progress continued on the laser weld shift, and on May 5, the FDA approved the Special PMA Supplement for Taxus and Express[2] with an order--which was publicly available on its website--stating that BSC had approval to implement "1) the addition of an additional in-process inspection, 2) modification of a current in-process inspection, and 3) modification of a manufacturing process to address complaints related to failure of the delivery system balloon to properly deflate following stent deployment." BSC began to implement these changes immediately.

The day that the FDA approved these changes, they were reported in a Merrill Lynch analyst report stating that BSC had "a manufacturing fix to address the issue of 'no deflates' submitted to the FDA to further reduce dependence on operator technique." Two days later, the Boston Globe ran a story that covered both this manufacturing solution to the no-deflate problem, as well as the sticky stent issue. As to the no-deflate problem, the article stated:

> [T]o prevent the problem of balloons failing to deflate, Boston Scientific is making a small change in the laser-bonding process it uses to join the balloon and catheter before the stent is packaged around them, said spokesman Paul Donovan. The change will not

> affect the company's earnings and won't lead to a recall of any of the thousands of Taxus packages that have been shipped but not implanted, he said.

As the article makes clear, Donovan differentiated between the no-deflate and sticky stent issues, explaining that the manufacturing change is "meant to address the problem of balloons failing to deflate," while the company "has no plans for manufacturing changes to address the other problem." The article reported that the company "believes the withdrawal problems are probably because of doctors' unfamiliarity with the new system."

On May 25, 2004, BSC learned that a patient had died due to complications from no-deflate. And in early June, BSC received a no-deflate complaint on one Taxus production lot for which there was a report of a previous failure. The remaining inventory for this batch was retrieved from the warehouse and a PIR update was commenced.

While the PIR update was ongoing, a June 22 Dow Jones Newswires article about Taxus reported that some doctors had experienced "a 'stickiness' that makes it somewhat difficult to withdraw auxiliary equipment after the stent is inserted," and that there had been "a smattering of reports of patients undergoing emergency surgery to deal with complications that arose during procedures with the stent." The article stated: "These issues will work themselves out once physicians get used to the product, the company says, and it recently made a manufacturing change to deal

with one problem doctors cited." The article quoted Paul Donovan, spokesman for Boston Scientific, as saying: "We had a similar experience in Europe where there was a learning curve early on and some initial problems, and then people got used to the product and the number of complaints subsided and the issue went away." The article then went on to more clearly differentiate between the no-deflate issue and the stickiness issue, stating: "Problems doctors have reported with Taxus include trouble getting the balloon to deflate and difficulty withdrawing the balloon catheter. Boston Scientific is making a change in its manufacturing process that will result in the balloons deflating more easily, Donovan said." The article also quoted one doctor as saying that he had not seen any Taxus devices that would not deflate, but that he experienced stickiness 60-70% of the time. It quoted multiple doctors saying that with practice, the stickiness issue was not a problem. The article also reported Donovan as saying that "[t]here won't be a recall" and describing the number of complaints as "tiny."

On the evening of June 22, the PIR team investigating the multiple-complaint lot of Taxus issued a PIR reporting three field complaints and four "out-of-box" failures (where the devices had become focally necked during manufacturing) for this lot. It reported that an examination of all remaining Taxus devices in the warehouse from lots manufactured adjacent to this lot found no problems. The PIR team recommended recalling the one lot. This

recommendation was sent to the Field Action Committee, which after conducting its review, decided on June 30 to institute the recall.

On June 30, 2004, an email from BSC's Regulatory Affairs Vice President Russell Felkey reported that he had spoken with someone at the FDA who inquired "why BSC isn't conducting a field action to remove product remaining in the field that was manufactured prior to our PMA Supplement that included corrective action for no-deflate." Felkey explained that he had told the FDA that the company was prepared to discuss this possibility fully, but that he had not "disclose[d] the pending recall since we haven't fully completed the approval process."

On July 1, BSC advised the FDA that it would be recalling the Maple Grove lot identified in the June 22 PIR. Later that day, it received a report from Galway that it also had a lot with multiple out-of-box failures. BSC informed the FDA of this, and on July 2, it recalled both lots.

During a July 2 conference call with analysts, CEO Jim Tobin explained that the recall affected only "two batches out of about 1,200 . . . that we've produced so far," emphasizing "we've learned a lot from this . . . that will help us avoid a repeat as we go forward." When asked if the company was "completely positive . . . that [the problem was] only in the two lots that were recalled -- that there might not be another lot out there that has maybe a couple of stents that had the same problem," he replied:

> You can't be completely sure until all of the work has been done to investigate every complaint. There will undoubtedly be more complaints that are somewhere in the pipeline, so there are still investigations to go, but those would be single batch, small number kind of situations based on what we think we know today.

He explained that the complaints were from lots produced before the introduction of the laser shift and that there had not yet been any complaints from devices manufactured after the manufacturing change, but emphasized that this "doesn't mean we won't." Management made clear that there had only been 20,000 of the newer devices shipped, so that if these lots "had a problem at the same rate we've been having, you would have expected maybe zero or one, two at the most. We haven't had any. What does that tell you? Nothing, because the sample is too small."

When asked how many pre-manufacturing change lots were in circulation, Tobin stated: "I don't know the number of lots, but the number of units is probably in the 100,000 range--somewhere around there." He stated that he did not believe that the limited recall was "a tip of the iceberg sort of situation, but it is what it is." Tobin explained: "We're looking at those batches for which we have complaints, which is 25 batches, or some number like that, out of 1,223. Of those 25, these two we're not happy with and we're pulling them back. The analysis is not complete, so it is possible that you would find another batch or two, but unlikely, I would say."

In discussing the laser shift, Vice President and CFO Larry Best[9] explained that the company had received complaints of no-deflates since it launched Express[2], that the company had "been working on this for quite a while," and that the manufacturing change was "in process before we launched Taxus and would have been submitted whether we got a complaint or not." He later emphasized: "This is not a fix that's being made in response to the Taxus launch or the Taxus complaints."[10]

Market analysts labeled the July 2 recall a minor event. A July 5 Goldman Sachs report stated: "In our opinion, the recall is a minor issue, which should have a negligible impact on the company's market position. . . . Based on management's comments, we believe that the issue has already been resolved and the recall is a remnant of a prior manufacturing process." It explained:

> The company indicated that there are only 42 complaints worldwide (out of which 12 could not be replicated) about the balloon deflation issue with Taxus stent system out of the more than 445,000 stents which have been implanted worldwide, which implies an incidence rate of 0.009%. US FDA has received reports of one death and 16 serious injuries associated with

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[9] Larry Best also spoke with caution, stating that the people working on the issue were "pretty confident that they've further reduced any incidence of no deflate, but who knows?"

[10] Plaintiff contends that this is contradicted by defendants' admission during a July 15 call that the laser shift was implemented in reaction to no-deflate complaints. There is no such contradiction. While the change to Express[2] was in response to the complaints, the decision to incorporate it into Taxus was based on the fact that Taxus used the same Express[2] catheter.

> balloon deflation and 8 reports of balloon malfunction that were not associated with patient injury, out of more than 220,000 US stents implanted, implying an incidence rate of 0.01%. These extremely low event rates suggest that the incidence of non-deflation is a rare occurrence (even with under-reporting) and not likely to grow to be a larger issue.

Similar details and evaluations were reported in a Harris Nesbitt analyst report on July 6.

Following the recall, BSC continued its investigation, as Jim Tobin stated it would in the July 2 conference call. Examining all devices remaining in inventory from any batch that had even a single no-deflate complaint, a team at Maple Grove made two discoveries. First, it found that by using laser pixel software that recorded detailed information regarding the precise location of the laser for each batch of catheters, it could identify lots in which a "laser event" affecting the laser alignment, as measured by pixel shifts, made the laser bonds more susceptible to tensile forces. Second, it found that the cone puffing process--in particular, the sliding of a protector over the stent prior to puffing--could create significant tensile forces on the distal outer when the balloon was atypically large, and that cone puffing was a "large differentiator between [Taxus] and Express^2 with respect to inflate/deflate issues." This was the first time that cone puffing was conclusively identified as a cause of no-deflates. Cone puffing had not been used in the manufacture of Express^2, nor in the manufacture of Taxus for sale outside the United States.

The director of Process Development in Research & Development at Maple Grove, Phil Ebeling, characterized the two discoveries as "epiphanies or aha moments" for him and his team.

Based on these two discoveries, BSC instituted another recall on July 16. This recall focused on devices that had been produced prior to the implementation of the reticle inspection in April 2004. Using laser pixel and cone puffing data for the pre-reticle inspection lots at Maple Grove, it was able to identify eight lots at risk for focal necking. In Galway, however, BSC did not have the laser software being piloted in Maple Grove, so as a precaution, it decided to recall all Taxus devices that had been manufactured at Galway prior to the introduction of the reticle inspection.

The recall covered 85,000 of the more than 500,000 Taxus devices that it had shipped.[11] In a press release announcing this recall, BSC explained that in total, it had received reports of one death and eighteen serious injuries associated with balloon deflation failure with Taxus devices.[12] The press release stated: "The Company implemented review of its manufacturing process, additional inspections, and an FDA-approved modification to the

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[11] As a further precaution, BSC also recalled 11,000 Express[2] devices that had been manufactured in Galway before the introduction of the May 2003 changes. It had shipped over 600,000 Express[2] devices.

[12] It also noted that it had received reports of two deaths and twenty-five serious injuries associated with Express[2] devices.

manufacturing process for these products. The current and future production are not expected to experience similar balloon deflation problems." The press release also stated that BSC expected the recall to impact its second quarter financial results, including a reversal of $45 million in sales and a write-down of $50 million in inventory.

Following the announcement of the expanded recall, BSC's stock price dropped. Plaintiff claims the investing shareholders represented by the class lost over $700 million.[13]

II.

Our review of a grant of summary judgment is de novo. City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 756 (1st Cir. 2011). Summary judgment is required when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

A. The Elements of Securities Fraud

For plaintiff to prevail on its claim that defendants violated Section 10(b) and Rule 10b-5, it must prove six elements: "(1) a material misrepresentation or omission; (2) scienter, or a

[13] After the July recall, BSC realized that it had made an error in calculating the manufacture dates for the recall, as the reticle inspection was not in place at Galway until 2.5 days later than it had originally thought. On August 5, BSC recalled the Taxus devices that had been manufactured at Galway during this time period.

wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Waters Corp., 632 F.3d at 756. This case turns on the second of these requirements, scienter, and the question of whether plaintiff has produced sufficient competent evidence that defendants acted with scienter to survive their motion for summary judgment.[14]

Scienter is an intention "to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 & n.12 (1976); see also SEC v. Ficken, 546 F.3d 45, 47-48 (1st Cir. 2008). Under this circuit's precedent, proving scienter requires "a showing of either 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)). Recklessness in this context means "a highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant

[14] "Although it is unusual to grant summary judgment on scienter, summary judgment on this issue is sometimes appropriate. 'Even in cases where elusive concepts such as motive or intent are at issue, summary judgment may be appropriate if the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation.'" SEC v. Ficken, 546 F.3d 45, 52 (1st Cir. 2008) (quoting Medina-Munoz v. R.J. Reynolds Tobacco Co., 896 F.2d 5, 8 (1st Cir. 1990)).

or is so obvious the actor must have been aware of it." SEC v. Fife, 311 F.3d 1, 9-10 (1st Cir. 2002) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999)) (internal quotation marks omitted).

Although this case turns on scienter, it is important to identify the related requirement of materiality. See BSC I, 523 F.3d at 87 ("Knowingly omitting material information is probative, although not determinative, of scienter."). As the Supreme Court recently stated in Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309 (2011), the "materiality requirement is satisfied when there is 'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" Id. at 1318 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)) (internal quotation marks omitted).

The Court explained that it was "'careful not to set too low a standard of materiality,' for fear that management would 'bury the shareholders in an avalanche of trivial information.'" Id. (quoting Basic, 485 U.S. at 231). But at the same time, the Court rejected the use of a bright line rule that "reports of adverse events associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product is in fact causing the events." Id. at 1318-19. The Court explained

that because "medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well." Id. at 1321.

The Court cautioned, however, that it was not holding that all adverse events must be disclosed. It stressed that Rule 10b-5 and Section 10(b) "do not create an affirmative duty to disclose any and all material information." Id. It explained that "disclosure is required under these provisions only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" Id. (quoting 17 C.F.R. § 240.10b-5(b)); see also Basic, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). The Court explained that "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market." Matrixx, 131 S. Ct. at 1322.

B. Plaintiff's Proposed Inference of Scienter

We understand plaintiff's case to rest in general on the claim that the defendants were aware of a risk that no-deflate problems with U.S. Taxus devices would require a significant recall; that the company's statements and omissions misled the market about the nature, cause, and degree of this risk; and that

these facts support an inference that defendants acted with scienter. Specifically, plaintiff argues that a reasonable inference of defendants' scienter is established by evidence that on three issues, defendants had "knowledge of facts or access to information contradicting their public statements." Evidence that "defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." Aldridge, 284 F.3d at 83. Here, however, plaintiff's evidence considered individually and as a whole makes clear that no reasonable jury could find that defendants recklessly misled the market about a significant risk of Taxus no-deflates or the need for a recall, much less that they intentionally did so.

1. Disclosure of the Laser Shift

Plaintiff argues that defendants' failure to implement the planned laser shift in November recklessly created a significant risk that the newly launched U.S. Taxus devices would need to be recalled and is evidence that defendants "acted with scienter in not disclosing the existence of the fix" sooner than they did.

At its core, this argument rests on the premise that the laser shift was not only the ultimate solution to the problem of focal necking, but also the criterion that defined whether or not a device needed to be recalled. This premise is flawed for a

number of reasons. First, there is no evidence that the laser shift was itself sufficient to prevent focal necking in Taxus; the fall 2003 conclusion by the six sigma team that the laser shift would prevent focal necking for Express^2 regardless of other causal factors did not apply to the causal factor of cone puffing, as cone puffing was not used in the manufacture of Express^2 and its relevance to focal necking in Taxus was not known until the summer of 2004. Second, the implementation of the laser shift was not a determinative criterion in the recall.

The July 16, 2004 decision about which lots of Taxus to recall was not based on whether they had been produced using the new laser alignment. Rather, the decision was based on whether the lots had been produced before or after the introduction of the reticle inspection at the end of April. The recall covered all Galway-manufactured devices that were manufactured before this, and none that were manufactured after it. Likewise, no devices manufactured in Maple Grove after this were recalled. While BSC was able to limit the recall of Maple Grove lots manufactured pre-reticle inspection by using manufacturing data not available in Galway, the introduction of the reticle inspection was nevertheless the defining moment in time. Therefore, although the laser shift was a manufacturing solution to focal necking that eliminated the

need for some of BSC's other solutions, it was not determinative of whether a product needed to be recalled.[15]

Plaintiff nevertheless contends that defendants were required to disclose the laser shift sooner than they did. It claims that BSC "was prepared to submit its change to the FDA by November 2003," but that "the process was aborted" by the Taxus PMA Council in order to keep the Taxus release on schedule, thereby misleading the market about the risk that it would be introducing a new product that had a manufacturing defect. It argues that "the decision to build inventory without the permanent fix in place made the recalls not just foreseeable, but probable."

There is no evidence in the record that supports this claim. The evidence is that as of November 2003, BSC had not validated the .8 mm laser shift and was not prepared to submit this documentation to the FDA, as it needed to do before implementing the change. Although plaintiff is correct that on September 2, the engineer leading the laser shift team, Kevin Griffin, "proposed a

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[15] Plaintiff's claim that the laser shift was a crucial manufacturing change is further weakened by the fact that it was also irrelevant to the recall of Express^2 devices. For Express^2, the recall fence was the May 2003 changes. The fact that the determinative date for Express^2 was the introduction of the May 2003 changes--and not the laser shift, or even the reticle inspection--also indicates that the causes of focal necking in Taxus devices were not, as plaintiff contends, identical to the causes in Express^2 devices. This further undermines plaintiff's claim that in November 2003, the Taxus PMA Council postponed the implementation of the validation plan for the laser shift on Express^2 despite awareness that it was a "critical fix."

validation plan for the laser shift that would be completed and submitted to the FDA by November 7, 2003," the email to which Griffin attached this plan also stated that it was "a bit optimistic." Likewise, while six sigma team leader Peter Delmer testified that the laser shift had been "confirmed" as a manufacturing solution to focal necking by October 2003, he also testified that at this point, "an awful lot more work would have to be done in order to implement" the manufacturing change. Further, the additional work that Griffin and Delmer said was required was in fact done. In October, the team had only recommended shifting the laser from .4 mm to .6 mm, rather than the .8 mm position that was ultimately implemented. It would have been inappropriate for the company to disclose that it was considering a manufacturing change before it was satisfied that the change would not itself cause other problems, and no inference of scienter can be drawn from this non-disclosure.

Moreover, Griffin's validation plan was created for Express^2 not Taxus--a fact that plaintiff ignores in arguing that the Taxus PMA Council modified the plan. Although both the Express^2 and Taxus systems were built using the same catheter, the teams worked independently and plaintiff cites no evidence that the validation plan and FDA submissions for Express^2 were influenced by the Taxus PMA Council's decision to only allow "critical"

modifications to the Taxus PMA after October 31.[16] On the contrary, when Griffin sent the validation plan to Paul Bulger and asked whether he should "keep the Taxus reg folks involved," Bulger replied: "I have informed Taxus regulatory of the proposed changes. They have not given any specific feedback or concerns. Since this is a change to the delivery system only, it should have a minimal impact to the Taxus PMA review."[17]

Moreover, no inference of scienter can be drawn from the fact that BSC management decided at the end of November that it did not immediately need to disclose or implement the laser shift. At this point, there had been only two no-deflate complaints for the tens of thousands of Express^2 and Taxus devices manufactured at Galway after the introduction of the May 2003 changes, and there had been only three no-deflates ever on Express^2 devices manufactured at Maple Grove. Based on the information available, no inference of scienter can be drawn from defendants' conclusion that the preventive measures implemented in May had been effective

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[16] After October 31, BSC did submit changes to the Taxus PMA. On November 11, it submitted a PMA Amendment notifying the FDA of the new elongation specification that it had already incorporated into Express^2.

[17] Plaintiff also states that the laser shift was included on BSC's submission schedule on October 6, but no longer on the list on October 29, due to the Council's decision. Its citations to the record do not support this claim. Both lists include the laser shift, and neither has a proposed submission date.

in further reducing what was already, by industry standards, a very low rate of complications.

Plaintiff also claims that later, "in the March-May 2004 time period, no Defendant affirmatively disclosed any . . . information" about "the approval of manufacturing changes" and "the fact that some pre-manufacturing change inventory remained in the field." However, it is clear that the market knew that BSC was implementing a manufacturing change to address no-deflates on May 5, when the FDA approved the Special PMA Supplement requesting permission to make the change. The FDA approval, which was publicly available on its website, informed the market that BSC was making a "modification of a manufacturing process to address complaints related to failure of the delivery system balloon to properly deflate following stent deployment." The change was also reported later that day in a Merrill Lynch analyst report, which stated that the company was implementing "a manufacturing fix to address the issue of 'no deflates.'" It would have been clear to the market that the stents produced prior to this date did not incorporate this modification.

2. Statements Regarding Physician Unfamiliarity

Plaintiff also claims that from April 2004 through the July 16 recall, BSC misled and lulled the market by maintaining that "the problems with Taxus were due to physician unfamiliarity with the device," rather than a manufacturing issue, and that

"[o]nly after the recalls did [BSC] admit that the defect in the catheter was manufacturing related." Plaintiff has produced no evidentiary support for its claim, having often conflated the no-deflate problem with the sticky stent problem and failed to differentiate between the problems and their causes.

Plaintiff claims that Senior Vice President Paul LaViolette misrepresented the cause of problems with the stent system, and lulled the market, when he said during the first quarter analyst conference call on April 20, 2004 that "essentially all complaint activity subsided" as physicians became accustomed to using Taxus. This statement was in response to a specific question in which an analyst asked about the sticky stent problem (not the no-deflate problem) and why there had been no reports of such a problem in Europe over the past 12 months. LaViolette explained that there had in fact been sticky stent complaints when Taxus was first launched in Europe, but that these complaints subsided as physicians became accustomed to using Taxus. He did not say that physician technique was the cause of the no-deflate problem.

Plaintiff also focuses on statements by BSC spokesman Paul Donovan, who was reported in a Boston Globe article on April 24 as saying that "a few doctors in Europe reported similar problems when Taxus was initially approved for use there last year, but the complaints ended as doctors became more comfortable with the stents." This was true as to the sticky stent problem, and as

the article reported, Donovan differentiated between the two problems. In discussing the 27 complaints that had been received, he explained that "in most of the reported cases the balloons . . . seemed to stick to the coating on the stent, creating a potential blockage. In about six of the cases the balloon wouldn't deflate, or would only deflate slowly."

It is true that not every article was as clear in differentiating between the 27 complaints, but no inference of scienter can be drawn from this fact. Plaintiff cites an April 26 Wall Street Journal article that stated:

> Boston Scientific said it has received 27 reports of difficulties removing or deflating the balloon used in the angioplasty. . . . It adds that it believes the problem will disappear once physicians gain experience using the Taxus. 'This sort of thing does tend to happen as physicians gain experience with the device,' said company Senior Vice President Paul LaViolette.

Even so, the article went on to state that "[c]opies of 21 of these reports reviewed by The Wall Street Journal showed that most of the complaints appeared to be minor annoyances, requiring the doctor to fiddle a bit to remove or deflate the balloon," apparently referring to the same break-down of complaints reported in the Boston Globe article. The fact that this Wall Street Journal article was not as clear as the Boston Globe in reporting that there were two different issues--no-deflate and sticky stent--and that physician familiarity solved the latter, does not support a

claim that defendants recklessly misled the market as to the cause of the complaints. This is especially so given that reports and statements issued over the next month clearly noted the different problems and solutions.

On May 5, the market had clear notice that BSC was not attributing the no-deflate problem to physician mishandling when the FDA announced approval of BSC's request for a "modification of a manufacturing process to address complaints related to failure of the delivery system balloon to properly deflate following stent deployment." The day that the FDA approved the change, it was reported in a Merrill Lynch analyst report stating that "the company has a manufacturing fix to address the issue of 'no deflates' submitted to the FDA to further reduce dependence on operator technique." And two days later, the Boston Globe ran a story that covered both the laser-shift solution to the no-deflate issue, as well as the sticky stent problem. As to the no-deflate issue, the article stated: "[T]o prevent the problem of balloons failing to deflate, Boston Scientific is making a small change in the laser-bonding process it uses to join the balloon and catheter before the stent is packaged around them, said spokesman Paul Donovan." The article makes clear that Donovan differentiated between the no-deflate and sticky stent issues, and their solutions, explaining that the manufacturing change is "meant to address the problem of balloons failing to deflate," while the

company "has no plans for manufacturing changes to address the other problem," which was sticky stent. Likewise, a May 27, 2004 Goldman Sachs report stated that "the worldwide rate of 'withdrawal resistance' (balloons sticking to the stent) is only 0.03%, which has largely been controlled through additional physician training," while "other issues, including the 0.0005% worldwide rate of 'deflation difficulty' (balloons unwilling to deflate following dilatation), were more-or-less corrected with slight adjustments implemented to the balloon catheter."

That physician experience and technique could solve complaints of stent stickiness continued to be clearly reported to the market in the following month. On June 22, a Dow Jones Newswires article stated: "Problems doctors have reported with Taxus include trouble getting the balloon to deflate and difficulty withdrawing the balloon catheter." As to the former, it noted that "Boston Scientific is making a change in its manufacturing process that will result in the balloons deflating more easily." It quoted one doctor as saying that he had not seen any Taxus stent systems that would not deflate, but that he experienced stickiness with them 60-70% of the time. It also quoted multiple doctors saying that with practice, the stickiness issue was not a problem.[18]

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[18] Plaintiff claims that this article also "reported that the Company had said that no-deflate problems 'will work themselves out once physicians get used to the product.'" (Emphasis added). This mischaracterizes the article. The relevant text of the article states: "Some doctors say there is extra effort associated

Given that market analysts and BSC management regularly differentiated between the two problems and their causes, there is no basis for plaintiff's contention that "[e]ven on July 2," after the first recall, "market analysts continued to believe that doctors' techniques were the problem behind no-deflate." In fact, the July 2, 2004 Merrill Lynch analyst report that plaintiff cites in support of this claim contradicts it. The report highlighted the manufacturing solution to the problem of no-deflates, explaining that BSC identified "a series of manufacturing events" that increased the risk of no-deflate; that the recall was based on these manufacturing lots; and that BSC had introduced "a manufacturing change in May that is meant to further reduce the incidence of 'no deflates.'" The report's only reference to the role of physician handling was a single sentence that noted that BSC was sending a letter to physicians to inform them of "handling issues that can prevent or mitigate" complications with no-deflate.

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with Taxus, including a 'stickiness' that makes it somewhat difficult to withdraw auxiliary equipment after the stent is inserted. There have also been a smattering of reports of patients undergoing emergency surgery to deal with complications that arose during procedures with the stent. . . . These issues will work themselves out once physicians get used to the product, the company says, and it recently made a manufacturing change to deal with one problem doctors cited." Although it is not entirely clear what the author of the article meant by "these issues," and this phrase can be read to include the no-deflate issue, this does not provide a basis for a reasonable inference of scienter, as the rest of the article--and many other articles--report BSC management as clearly differentiating between the two different issues and their solutions.

This does not blame physicians for the problem. Rather, it says that physicians could be part of a solution that was being primarily achieved through a manufacturing change.

3. Statements Regarding Recall Risk

Plaintiff claims that the July recalls were foreseeable and that BSC should have disclosed the risk sooner. They state that "a recall of Taxus was not merely in the universe of risks recognized by Defendants, it was a certain risk known to the Defendants, thus transforming this case from one of mere negligence to one of deliberate indifference." Plaintiff's proposed inference of scienter is not only based on what defendants failed to say about the introduction of the laser shift, discussed above, but also on what they did say about the risk of recall. Plaintiff argues that defendants affirmatively misled the market about this risk.

Plaintiff claims that starting in April 2004, BSC told the market "that there would be no recall of devices manufactured prior to the implementation of the FDA-approved manufacturing change," and that "[e]ven on June 22, the date the Company had determined a recall was necessary, the Company continued to make statements that there would be no recall." The evidence does not support these claims.

Plaintiff points to the fact that a June 22 Dow Jones Newswires article reported Paul Donovan as saying there would not

be a recall, while a June 22 PIR recommended the recall of one batch of Taxus devices manufactured in Maple Grove. However, the PIR was not completed until the evening of June 22, while the article was published in the morning. It is also unclear from the article when Donovan made this statement. Further, standard company protocol required that PIR recommendations be evaluated and approved by the FAC, and the FAC did not make its final decision to institute the recall until about a week later on June 30.

Plaintiff also argues that CEO Jim Tobin misrepresented the known risk of a second recall when, during the analyst call on July 2, he said that he did not believe that the recall was a "tip of the iceberg sort of situation." Plaintiff argues that this statement is inconsistent with an email that Tobin sent earlier in the day in which he mentioned that he was "not totally confident" that everything was "under control," expressing concern that he had just learned that twenty more lots were being tested in Galway.

The two statements are not inconsistent and do not support an inference of scienter. Subsequent emails made clear that the company was assessing the risk of receiving additional complaints on the twenty lots for which there had been only one complaint, and was not in fact testing any of these devices in these lots. Further, plaintiff fails to note that Tobin expressly discussed this during the conference call. In response to a question about future recalls, Tobin explained: "We're looking at

those batches for which we have complaints, which is 25 batches, or some number like that, out of 1,223. Of those 25, these two we're not happy with and we're pulling them back. The analysis is not complete, so it is possible that you would find another batch or two, but unlikely, I would say."[19]

During the July 2 conference call, Tobin even expressly identified the risk that there could also be complaints for the lots produced after the introduction of the laser shift. He explained that BSC had not received any complaints about devices manufactured after the introduction of the laser shift, but emphasized that this "doesn't mean we won't." This discussion with analysts made clear that because only 20,000 post-laser shift devices had shipped, and the historical rate of error was very low, the fact that there had been no complaints so far meant "[n]othing, because the sample is too small." Defendants were clear about the risk of another small recall.[20]

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[19] In response to another question on this topic, he emphasized this point, stating that the company could not be sure that the problems were only in the two lots that were recalled "until all of the work has been done to investigate every complaint." He explained: "There will undoubtedly be more complaints that are somewhere in the pipeline, so there are still investigations to go, but those would be single batch, small number kind of situations based on what we think we know today."

[20] This caution was also reported by market analysts. A July 2 report from Morgan Stanley stated, "we believe that it is reasonable to expect that there could be a similar announcement over the next few months potentially pertaining to other batches with similar problems."

There is no evidence that management had reason to suspect a recall on the order of the second recall, much less that they recklessly or intentionally misled the market about it, such as to permit an inference of scienter. Rather, the evidence is that it was not until after July 2 that the company recognized the significance of the factors that provided the basis for the second recall. Defendants testified that it was not until after the first recall that the company recognized that the cone puffing process was creating tensile forces on the devices significant enough to cause focal-necking, and plaintiff fails to identify any evidence that draws this testimony into question.

Plaintiff argues that defendants' account of when they learned of the role of cone puffing is contradicted by an internal report circulated on March 23, 2004 stating that the "loading of the balloon protector after folding and after cone puffing has been highly suspected" as a source of "high tensile forces during processing." But plaintiff fails to note that the report then states "but we have not been able to draw direct correlation to focal necking" and concludes that additional research "activities need to be started to assess the tensile forces that are being applied at various processes (i.e. balloon folding & cone puffing)."

Plaintiff also argues that defendants' account of the role of cone puffing in no-deflates and the recall is contradicted

by an email from BSC engineer Ken Pucel on August 24, 2004 stating that there was "too much uncertainty" to draw a definitive conclusion about whether cone puffing was causing the rate-increase for Taxus no-deflates. However, Pucel's email also stated that "there is good reason to suspect conepuffing," noting that Galway's no-deflate complaint rate increased from 15 ppm to 240 ppm after the introduction of cone puffing and concluding that the company "need[ed] to have a six sigma black belt further analyze the data." Even if this August email indicated what defendants knew in early July, rather than late August, it would do nothing to undermine defendants' evidence that the second recall was instituted in part because of new information they learned about the risk of focal necking due to cone puffing.[21]

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[21] Plaintiff also suggests that BSC misled the investing public about the risk of recall in failing to affirmatively disclose no-deflate complaints. In fact, BSC reported the no-deflate complaints to the FDA in Medical Device Reporting (MDR) reports, which were publicly available on the FDA website. These MDRs were regularly cited in analyst reports on BSC. For example, on April 27, 2004, Goldman Sachs released a report reiterating its buy rating for BSC, explaining that it had "conducted a review of the most recently available adverse event reports (MDR's) for the Taxus stent in the FDA database" and "conclude[d] that the nature of the adverse events is within the scope of what can be expected in the early stages of a new interventional product launch." It reported that "the current rate of adverse events on a worldwide basis is extremely rare at 0.01% or 11.8 per 100,000 cases." Plaintiff argues that BSC did not accurately report complaints to the FDA, noting that in 2005, the FDA cited BSC for failing to comply with its disclosure obligations. The FDA review found that "from January 2004 to June 2005, 66 MDR reports of death or serious injury were not submitted within 30 days." However, plaintiff cites no facts that would support an inference of scienter. It does not specify what fraction of the 66 complaints in these 18

C. The Grant of Summary Judgment

In considering defendants' motion for summary judgment, we must look at the record in the light most favorable to plaintiff and indulge all reasonable inferences in its favor. Evans Cabinet Corp. v. Kitchen Int'l, Inc., 593 F.3d 135, 140 (1st Cir. 2010). Plaintiff, however, must nonetheless "put forth specific facts to support the conclusion that a triable issue subsists." Martínez-Rodríguez v. Guevara, 597 F.3d 414, 419 (1st Cir. 2010). Evidence that "is merely colorable or is not significantly probative" cannot defeat the motion. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50 (1986). With respect to each issue on which plaintiff has the burden of proof at trial, it must "present definite, competent evidence to rebut the motion," Martínez-Rodríguez, 597 F.3d at 419 (quoting Vineberg v. Bissonnette, 548 F.3d 50, 56 (1st Cir. 2008)) (internal quotation marks omitted), and as our review of the facts and plaintiff's claims makes clear, plaintiff has failed to produce evidence that would support a reasonable inference that defendants acted with scienter.

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months occurred during the first few months at issue here, nor does it identify how many of these were due to no-deflate, which was generally responsible for only a small fraction of total complaints. Further, while the FDA report notes that some of the under-reporting was due to human error, it does not suggest that this was intentional or reckless. Moreover, market analysts repeated throughout the class period that the rate of complaints was so low that even assuming under-reporting, they believed the complaints were a minor issue unlikely to affect the stock price.

A statement or omission is only actionable if, at the relevant time, defendants knew, or were reckless in not knowing, of material information that they were obligated to disclose and acted intentionally or recklessly in failing to disclose it. See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008); see also ACA Fin., 512 F.3d at 62 (statements were not materially misleading where there was "nothing . . . to establish that the defendants were aware of facts, at the time they made their predictions, that would have made those predictions unreasonable"); BSC I, 523 F.3d at 86 ("Securities actions raise questions of what corporate managers knew and when they knew it.").

As to the laser shift, the key issue is not whether defendants were aware that the change was being contemplated, as plaintiff suggests, but rather whether they were aware or recklessly unaware that the no-deflate problem threatened Taxus's viability and hence the price of BSC's stock. See Detroit Gen. Ret. Sys. v. Medtronic, Inc., 621 F.3d 800, 809 (8th Cir. 2010) ("[T]he material question . . . is whether [the medical] devices were known to exceed acceptable failure rates overall."); In re Carter-Wallace, Inc., Sec. Litig., 220 F.3d 36, 41 (2d Cir. 2000) (focusing on whether defendants had sound reason to doubt the "commercial viability" of product); Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc) (distinguishing between

allegations of "commercial failure" and allegations of undisclosed details relating to risks); see also Biogen IDEC, 537 F.3d at 48-50. Plaintiff did not produce evidence that would support a reasonable inference that defendants intentionally or recklessly misled the public about such a risk.

A company does not commit securities fraud merely by failing to disclose all non-public material information that it possesses. ACA Fin., 512 F.3d at 61. Disclosure is required only when necessary "to make . . . statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b); Matrixx, 131 S. Ct. at 1321. Given the statements and disclosures that defendants did make, they had no obligation to disclose the fact that they were working on an improvement that would reduce the very small number of no-deflate complaints that they received, and of which the market was aware. Cf. Geffon v. Micrion Corp., 249 F.3d 29, 37 (1st Cir. 2001) (finding that although the defendant "could have provided still more information" regarding an alleged omission, "its failure to do so does not mean that the omission was purposely deceptive in a manner actionable under Rule 10b-5").

The investing public was not only aware of the no-deflate complaints, but also of the risk of recall, which defendants openly discussed. "To the extent that the plaintiff's complaint is that the precise degree of risk was not stated, that failure is not

sufficient to have rendered the statements misleading." Hill v. Gozani, 638 F.3d 40, 60 (1st Cir. 2011) (emphasis added).

While a statement of risk "does not insulate the speaker from liability . . . neither does it create liability simply because it does not disclose, at the level of detail the plaintiffs request in retrospect, all of the factors that contribute to the risk assessment." Id.; see also Backman, 910 F.2d at 16 (company disclosure that product was being sold below cost need not say how much below or that sales were below expectations). As we stated in Hill, "where the level of risk is unknown and the existence of a risk is disclosed, we shall hesitate to conclude that disclosure is misleading merely because it did not state that the risk was 'serious.'" Hill, 638 F.3d at 60.

Our conclusion as to scienter does not change when we consider plaintiff's insider trading claims. Cf. Waters Corp., 632 F.3d at 760-62; Biogen IDEC, 537 F.3d at 55-57. Insider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence. BSC I, 523 F.3d at 92. No such evidence exists here. While there were stock trades during this period, they did not suggest there was trading based on insider information. We agree with the district court that the nature and circumstances of defendants' trades would not in any event support an inference of scienter for the reasons the court identified. See In re Boston Sci. Corp., 708 F. Supp. 2d at 126-27.

Because plaintiff failed to produce evidence that would support a reasonable inference that defendants acted with scienter, the district court properly granted defendants' motion for summary judgment on the Section 10(b) and Rule 10b-5 claims. Because plaintiff's Section 20(a) claim was derivative of the Rule 10b-5 claim, it was properly dismissed as well. See 15 U.S.C. §§ 78t(a), 78t; Waters Corp., 632 F.3d at 762.

III.

In addition to appealing the district court's grant of defendants' motion for summary judgment, plaintiff appeals the court's denial of its motion to compel production of certain documents that defendants claimed were privileged. Almost all of these documents were generated in connection with an internal company investigation of the July 2004 recalls that was instituted in late August 2004 at the request of BSC's general counsel, Paul Sandman, in response to inquiries by the SEC and DOJ. The district court reviewed these documents in camera. Concluding that they were protected by either or both attorney-client privilege and work product privilege, it denied plaintiff's motion to compel production.[22]

[22] After these documents were reviewed in camera, they were returned to defendants and did not become part of the record. Plaintiff subsequently moved to have these documents added to the record but treated as confidential for purposes of appellate review of the court's denial of its motion to compel production. On February 7, 2011, the district court granted plaintiff's motion. The documents have been provided to us.

When an appeal concerns "a claim of privilege, the standard of review depends on the precise issue being litigated." In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.), 348 F.3d 16, 21 (1st Cir. 2003). We review a district court's evidentiary decisions for abuse of discretion, its underlying findings of fact for clear error, and questions of law de novo. Id. The fact that the district court did not provide a detailed account of its reasoning does not change the standard. Id. at 21-22.

Attorney-client privilege protects communications made in confidence by a client and a client's employees to an attorney, acting as an attorney, for the purpose of obtaining legal advice.[23] See Upjohn Co. v. United States, 449 U.S. 383, 394-95 (1981). "By safeguarding communications between client and lawyer, the privilege encourages full and free discussion, better enabling the client to conform his conduct to the dictates of the law and to present legitimate claims and defenses if litigation ensues." In re Keeper of Records, 348 F.3d at 22.

[23] More specifically, eight criteria must be met: "(1) Where legal advice of any kind is sought (2) from a professional legal adviser in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself or by the legal adviser, (8) except the protection be waived." Cavallaro v. United States, 284 F.3d 236, 245 (1st Cir. 2002) (quoting 8 J.H. Wigmore, Evidence § 2292, at 554 (McNaughton rev. 1961)).

Plaintiff argues that accidentally disclosed documents from BSC's internal "Recall Investigation Working Group" (RIWG) reveal that its investigation was a post-mortem on the recall to help the company avoid similar problems in the future and was unrelated to the provision of legal advice. The fact that communications between the RIWG and BSC's attorneys focused on ways to prevent similar mistakes in the future does not, however, remove them from attorney-client privilege. On the contrary, this type of information was highly relevant to BSC's potential liability and consequently directly related to providing legal advice to BSC's management.[24]

Plaintiff also argues that defendants "funneled" documents unrelated to legal advice through attorneys to "cloak[]

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[24] Plaintiff makes a similarly unavailing argument about work product privilege. The work-product doctrine protects documents prepared by an attorney if, "in light of the nature of the document and the factual situation in the particular case, the document can be fairly said to have been prepared or obtained because of the prospect of litigation." Maine v. U.S. Dept. of Interior, 298 F.3d 60, 68 (1st Cir. 2002) (quoting United States v. Adlman, 134 F.3d 1194, 1202 (2d Cir. 1998)) (internal quotation mark omitted); see also Fed. R. Civ. P. 26(b)(3). Plaintiff claims that the accidentally disclosed documents reveal that they were produced "not in anticipation of litigation, but for the purpose of specifying future 'improvement opportunities.'" But an attorney's work product does not lose protection merely because it is also "intended to inform a business decision influenced by the prospects of the litigation," Maine, 298 F.3d at 68 (quoting Adlman, 134 F.3d at 1197-98), and the evidence is clear that the RIWG was instituted because of the prospect of litigation. See also Adlman, 134 F.3d at 1198-99 ("Nothing in the Rule states or suggests that documents prepared 'in anticipation of litigation' with the purpose of assisting in the making of a business decision do not fall within its scope.").

the documents with a claim of privilege," citing accidentally disclosed documents showing that RIWG members were instructed to and did send written communication to each other through BSC's general counsel and in-house counsel. In taking steps to protect attorney-client privilege--such as telling the RIWG that all written communication should go through BSC's attorneys and that RIWG members should not directly write to each other--BSC's general counsel did not manufacture privilege but rather protected it when the communications were made for the purpose of providing requested legal advice. Cf. Upjohn Co., 449 U.S. at 394-95 (employees were given "explicit instructions" by company management to treat communications as "highly confidential" by not sharing them with others during an investigation directed by in-house counsel).

There is nothing in the documents that plaintiff identifies or in the confidential documents that we have reviewed that provides a basis for reversing the district court's denial of plaintiff's motion to compel their production.

IV.

We affirm entry of judgment for defendants. Costs are awarded to defendants.