IN RE: ST. JUDE MEDICAL, INC. SECURITIES LITIGATION Doc. 206

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
06-CV-1379(JMR/FLN)

In re: St. Jude Medical, Inc.,)
Securities Litigation ) ORDER

This case asks whether you can switch horses in midstream. Plaintiff-investors filed a class action securities fraud suit against St. Jude Medical, Inc., a St. Paul-based medical device manufacturer. Plaintiffs' consolidated and amended complaint accuses defendants (collectively referred to as "St. Jude") of forcing improper bulk sales of implantable cardioverter defibrillator devices in the fourth quarter of 2005, a technique referred to as "channel stuffing." (Am. Compl. ¶ 28.) In their amended complaint, plaintiffs allege defendants' channel stuffing led to overstated revenue expectations for the first quarter of 2006. They further claim St. Jude's management knew, but failed to disclose or recklessly disregarded the fact that, in overstuffing its customer supply lines, St. Jude actually suppressed demand for ICD sales into the new year.

After completing discovery, however, plaintiffs' entire theory changed. They now claim defendants failed to report slowing medical device sales prior to a first quarter 2006 income announcement to the public. As a corollary to this argument, plaintiffs have jettisoned their claims of channel stuffing.

Defendants move for summary judgment, arguing plaintiffs'

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reliance on a new theory circumvents the Private Securities Litigation Reform Act's ("PSLRA") heightened pleading standard for securities cases. Plaintiffs survived defendants' motion to dismiss on the channel stuffing theory. Defendants claim plaintiffs cannot now be permitted to survive summary judgment on a different theory.

Regardless of which horse plaintiffs ride, defendants claim plaintiffs cannot sustain any claim of securities fraud. Plaintiffs reply that genuine issues of fact remain, and particularly deny they "are attempting to morph their case into one that substantially differs from the Complaint." (Pls.' Mem. Opp'n Summ. J. 43.)

For the reasons set forth herein, the Court grants defendants' motion for summary judgment.

I. Background

St. Jude develops, manufactures, and distributes medical devices.[1] Among these are implantable cardioverter defibrillators ("ICDs"), which correct irregular heartbeats. St. Jude sells its ICDs two ways: (1) a doctor may purchase ICDs from St. Jude sales representatives on a patient-by-patient basis; or (2) St. Jude

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[1] The Court considers all facts in the light most favorable to plaintiff, the non-moving party. Because the motions are considered pursuant to Rule 56 of the Federal Rules of Civil Procedure, any "facts" the Court "finds" are taken from the parties' pleadings, and are not to be considered as determinations on the merits.

sales staff may sell ICDs to hospitals in bulk. Hospitals making bulk purchases enjoy a "quantity purchase" discount. Typically, bulk sales occur in the third month of each financial quarter, resulting in sales volume increases at the end of each quarter.

St. Jude competes with Medtronic, Inc., and Guidant Corp., two other ICD manufacturers. In the first half of 2005, both of these competitors recalled several thousand ICDs. The recalls created an opportunity for St. Jude to increase its share of the ICD market.

Plaintiffs contend defendants exploited this opportunity beyond the recall-induced increase by engaging in channel stuffing. In particular, plaintiffs' amended complaint alleges defendants accelerated 2005 sales by providing discounts to bulk ICD purchasers, offering favorable credit terms, promising to accept returns from hospitals making bulk purchases, and increasing commissions for agents making bulk sales. (Am. Compl. ¶¶ 32, 33, 34, 37, 39, 42.) Plaintiffs also accuse St. Jude of overpaying its sales force, who then funneled funds to doctors to encourage additional bulk purchases. (Am. Compl. ¶ 42.) The amended complaint concludes St. Jude's channel stuffing "cannibalized" its 2006 first quarter sales. (Am. Compl. ¶ 44.) In sum, St. Jude artificially over-supplied customers who essentially quit making ICD purchases in the next quarter.

A. Earnings Report & Guidance

On January 25, 2006, St. Jude announced fourth quarter 2005

ICD sales of $280 million – a 62 percent increase in sales from the same quarter of the previous year. (Am. Compl. ¶¶ 51-52.) St. Jude reported that these results "continued to underscore the competitiveness of St. Jude Medical's ICD product portfolio and program." (Id.) Plaintiffs maintain this earnings announcement misled investors because defendants knew, "but failed to disclose or recklessly disregarded," that these sales resulted from ICD-stuffed retail channels.

Plaintiffs claim St. Jude relied on the inflated 2005 results to support false predictions of 2006's first quarter ICD sales of $300-330 million worldwide. (Am. Compl. ¶ 57.) St. Jude counters that it derived sales estimates from legitimate sources: its Cardiac Rhythm Management Division's estimate of the total U.S. ICD market, and its U.S. Sales Division's estimate of anticipated ICD sales.

B. Alleged Misstatements

The amended complaint accuses defendants of issuing material misstatements throughout the first quarter of 2006, citing comments made January 25, 2006; February 10, 2006; and March 7, 2006.

- January 25, 2006: St. Jude's CEO, Daniel J. Starks, held an investor conference call. He noted St. Jude's four point increase in global ICD market share in 2004, and four or five more points in 2005, concluding, "[w]e're well positioned to continue gathering global ICD market share in 2006 and beyond . . . . [The company is] confident that [the ICD market] will continue to be a very strong growth market." (Am. Compl. ¶ 56.)

- That same day, John C. Heinmiller, St. Jude's Executive Vice President, recognized "[f]alling expectations for sales of Guidant's ICDs during the quarter might have led to unrealistically high hopes for St. Jude's devices." Despite these concerns, he emphasized the company headed into "2006 with nothing holding back" the ICD program. (Am. Compl. ¶ 58.)

- January 25, 2006: During a health care conference, CEO Starks called St. Jude's ICD the "highest profile component for our sales mix." He summarized the company's growth and predicted St. Jude would "continue gaining share going forward." (Am. Compl. ¶ 59.)

- February 10, 2006: During an annual analyst meeting, CEO Starks said St. Jude was "well positioned to continue taking [ICD] market share." He said the company "continued to expand" its share in the ICD market during 2005's fourth quarter and expected further gains. (Am. Compl. ¶ 63.)

- March 7, 2006: During a research conference presentation, Michael Coyle, St. Jude's Cardiac Rhythm Management Division President, predicted "strong growth." The company "[would] continue to focus our business on market share capture . . . ." (Am. Compl. ¶ 65.)

Plaintiffs' memorandum opposing summary judgment juxtaposes these statements against internal St. Jude communications indicating the company could not meet ICD sales projections. In part, plaintiffs point to St. Jude sales personnel's advice to superiors stating the company's 2006 sales goals were unrealistic. (Pls.' Mem. Opp'n Summ. J. 11.) Plaintiffs also point to a March 4, 2006, report indicating period sales were 19 percent below projections. (Id. at 14.) They further cite a March 6, 2006, meeting at which defendant Michael Rousseau remembers discussing St. Jude was facing "a significant miss." (Rousseau Dep. 76:9-18.) On March 22, 2006, U.S. Division management met with St. Jude's

senior executives to discuss ICD sales and acknowledged a bulk purchase “hangover in a slowing market,” because hospitals were sitting “on stacks of owned inventory from all three vendors.” (Pls.’ Ex. 81 at STJ237797.)

On April 4, 2006, St. Jude announced it would not meet 2006 first quarter income projections. The next day, St. Jude’s shares declined 12.7 percent. ICD sales missed projection by $38 million.

Thereafter, St. Jude’s CEO asked key personnel to investigate the shortfall. Their investigation found overall ICD market growth slowed, and Guidant had regained market share lost after its 2005 recalls. (Defs.’ Exs. 33, 44-45.)

C. The Suit

Plaintiffs brought a class action against St. Jude on behalf of all persons who purchased St. Jude common stock between January 25, 2006, and April 4, 2006 (“class period”). In Count 1 of the amended complaint, plaintiffs accuse defendants of violating Section 10(b) of the Exchange Act and SEC Rule 10-b5. Plaintiffs allege defendants misled and injured investors by inflating St. Jude’s stock price. In Count 2, plaintiffs claim individual St. Jude employees violated Section 20(a) of the Exchange Act, naming Daniel J. Starks, St. Jude’s Chief Executive Officer and President; John C. Heinmiller, St. Jude’s Chief Financial Officer; Michael J. Coyle, President of St. Jude’s Cardiac Rhythm Management Division; and Michael T. Rousseau, President of the U.S. Division.

On March 6, 2007, plaintiffs faced and survived defendants’

motion to dismiss under the Private Securities Litigation Reform Act and Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."). Thereafter, plaintiffs conducted discovery, and on October 14, 2008, defendants filed for summary judgment pursuant to Fed. R. Civ. P. 56. Plaintiffs oppose summary judgment, arguing genuine issues of fact remain as to whether St. Jude employees continued to issue optimistic statements concerning the ICD market, even though they realized St. Jude could not meet 2006 earnings projections. Plaintiffs now claim defendants had a duty to update the market when its prior earnings guidance became unrealistic. Defendants reply that this argument represents a new, unpled theory, and, regardless of which theory plaintiffs espouse, they have failed to establish a prima facie case of fraud.

II. Discussion

A. Standard

Summary judgment is appropriate when the evidence, viewed in the light most favorable to the nonmoving party, presents no genuine issue of material fact. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). This Court examines the evidence in the light most favorable to the non-moving party, giving that party the benefit of all inferences. Hammond v. Northland Counseling Ctr., Inc., 218 F.3d 886, 891 (8th Cir. 2000). The moving party is entitled to summary judgment if "the nonmoving party has failed to make a sufficient showing on an essential

element of her [or his] case with respect to which she [or he] has the burden of proof." Id.

B. Duty to Update

Defendants claim plaintiffs have abandoned their original theory of the case, and now offer a new, unpled theory of fraud. Plaintiffs' consolidated and amended class action complaint accuses St. Jude of channel stuffing by making improper bulk ICD sales and overstocking its purchasers. The amended complaint is the document as to which discovery was conducted, and is the only complaint before the Court.

At this time, plaintiffs claim St. Jude knowingly misled the market by failing to report slow or declining first quarter ICD sales prior to its April 4, 2006, announcement. This present theory relies on statements made by defendants on March 7, 2006, and March 9, 2006. There is neither a reference nor an allusion to these statements in the amended complaint. The amended complaint does, however, refer to statements issued January 25, 2006, February 10, 2006, and March 7, 2006.

In 1995, Congress passed the PSLRA to "enable district courts to weed out meritless class actions alleging fraud in the purchase and sale of securities." Siepel v. Bank of Am., 526 F.3d 1122, 1126 (8th Cir. 2008). In enacting the PSLRA, Congress mandated that private securities complaints "specify each statement alleged to have been misleading," as well as the "reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). The

amended complaint in this case is utterly silent concerning any assertion that St. Jude misled the market by failing to report slowing sales in the first quarter of 2006. Plaintiffs' new theory does not meet the PSLRA's requirements.

This Court, however, may consider the addition of new issues as a motion for leave to amend the amended complaint. See Fed. R. Civ. P. 15(a)(2). Under Rule 15, a court should grant leave to amend freely "when justice so requires." Id. A court may deny leave to amend, however, in the face of "undue delay, bad faith on the part of the moving party, futility of the amendment or unfair prejudice to the opposing party." United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006).

Plaintiffs deny they propose a new theory; they "merely wish to address" statements not included in the amended complaint. Plaintiffs argue that using these statements does not deprive defendants of "fair notice, deny possible discovery, nor [impair] Defendant's ability to present a full defense of its case" because defendants knew plaintiffs' case relied on the statements at issue. (Pls.' Mem. Opp'n Summ. J. 43.) Plaintiffs, then, remind the Court that "[m]otions to amend the pleadings to conform to the evidence under Rule 15(b) can be made at any time." See Kim v. Nash Finch Co., 123 F.3d 1046, 1062 (8th Cir. 1997). Rule 15 notwithstanding, plaintiffs have made no motion to amend.

More importantly, plaintiffs' memorandum opposing summary judgment goes far beyond "merely" offering additional statements

supposedly similar to those in the amended complaint. It wholly abandons the amended complaint's channel stuffing theory. The amended complaint uses various locutions of "channel stuffing" or "stuffing" no fewer than nine times. Their memorandum opposing summary judgment abandons the concept, never using the phrase "channel stuffing" again.

Further amendment at this late stage would defeat the PSLRA's purpose. See N.J. Carpenter Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 57 (1st Cir. 2008) (noting the PSLRA's deliberate scheme is "thrown into disarray when new theories are first produced in response to a motion to dismiss"). Plaintiffs survived a motion to dismiss in light of the theories they, themselves, chose; they may not now evade Congress's PSLRA mandates by switching horses midstream and pursuing a new theory. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 327 (2007) ("It is the federal lawmaker's prerogative . . . to allow, disallow, or shape the contours of – including the pleading and proof requirements for - § 10(b) private actions.").

Although the Eighth Circuit Court of Appeals has not spoken to this question, several courts have refused to consider new theories and material misstatements not previously included in a securities fraud complaint. See, e.g., Kaplan v. Rose, 49 F.3d 1363, 1369-72 (9th Cir. 1994) (affirming district court's refusal to consider material misstatements not included in the second amended complaint); In re: Bristol-Myers Squibb Sec. Litig., 228 F.R.D.

221, 228 (D.N.J. 2005) (allowing plaintiffs to add new statements to the amended complaint, after defendants filed for summary judgment, "would surely prejudice Defendants"); Fry v. UAL Corp., 895 F. Supp. 1018, 1050 (N.D. Ill. 1995) (finding plaintiffs "unduly delayed in seeking to amend their amended complaint to properly allege a duty to update claim"). The Court, then, must address plaintiffs' amended complaint as pleaded.

C. Securities Fraud

The Securities Exchange Act of 1934 affords a private cause of action to victims of securities fraud. See Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005). The basic elements of a securities fraud claim include: a material misrepresentation (or omission); scienter; a connection with the purchase or sale of security; reliance; economic loss; and loss causation, a causal connection between the material misrepresentation and the loss. Id. Here, the Court finds plaintiffs have failed to establish that defendants issued material misstatements, and have likewise failed to demonstrate that defendants acted with the requisite scienter.

1. Material Misrepresentations

The claimed misstatements logically fall into three categories: statements summarizing fourth quarter 2005 ICD sales; earnings guidances for first quarter 2006; and statements made January 25, 2006, February 10, 2006, and March 7, 2006 concerning the ICD market.

a. Materiality

Material statements are those which significantly impact a reasonable investor's mix of information. See Basic v. Levinson, 485 U.S. 224, 231-32 (1988). While materiality is usually a jury question, "[w]here a reasonable investor could not have been swayed by an alleged misrepresentation" courts may find an alleged misrepresentation immaterial. Parnes v. Gateway 2000, Inc., 122 F.3d 539, 546 (8th Cir. 1997). For example, "soft, puffing statements generally lack materiality because the market price of a share is not inflated by vague statements predicting growth." Id. at 547. Forward-looking statements, accompanied by "meaningful cautionary" language, are also considered immaterial, and are protected under the PSLRA's safe harbor. 15 U.S.C. § 78u-5(c).

Applying these principles, the Court holds, as a matter of law, that the statements made on January 25, 2006, February 10, 2006, and March 6, 2006, constituted mere "puffing." A statement saying St. Jude was "well positioned" to continue gathering market share, and expected "to continue gaining market share going forward" would not influence investor behavior. See In re: Hutchinson Tech., Inc., 536 F.3d 952, 956 (8th Cir. 2008) (agreeing with district court that company's statement it was "well-positioned on a number of new" programs constituted mere puffing). Similarly, statements saying the company's ICD program was "competitive," heading into 2006 "with nothing holding back [its] program," or continued to "expect to see strong growth," are not

material to investment decisions. Generalized statements concerning future success of a company's products and sales programs are commonplace. Nothing in these statements, however, would alter a reasonable investor's behavior.

Beyond this, St. Jude's 2006 revenue projections fall under the PSLRA's "safe harbor" for forward-looking statements accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i). Forward-looking statements include "projection[s] of revenues" and statements "of future economic performance." 15 U.S.C. § 78u-5(i). In In re: AMDOCS Ltd. Securities Litigation, the Eighth Circuit found a company's warning that "carriers are being very careful about committing to new expenditures" constituted an acceptable cautionary statement for investors. 390 F.3d 542, 548 (8th Cir. 2004). Here, on February 10, 2006, St. Jude's CEO said the "short-term impact from disruptive market dynamics" in the ICD market could "bring the growth rate down." (Riebel Aff. Ex. 46, 6.) On November 8, 2005, the company disclosed the risk of "pressures or preferences for alternative therapies." (Langdon Decl. Ex. 13, 35.) And, on March 16, 2006, the company's 10-K release warned that "[c]ompetitive pressures will increase in the future." (Langdon Decl. Ex. 11, 8.) The company's November 8, 2005, projection identified risk factors which might affect its predictions, including reductions in the

number of procedures using its devices caused by cost-saving pressures or alternate therapies and safety or performance concerns about its products. (Langdon Decl. Ex. 13, 35.)

Plaintiffs respond, claiming defendants' projections fall beyond the safe harbor's ambit. They do so claiming, not that the predictions were wrong, but rather, that the company possessed contrary information it was obligated to disclose. They further maintain any "cautionary language" was not meaningful or specific enough to afford safe-harbor protection. Plaintiffs are wrong.

Defendants' "cautionary language," touching cost-conscious reductions in ICD procedures, alternative therapies, and fears or reticence about ICDs themselves, accurately predicted real-world events which decreased ICD sales. These were the same factors "discovered" by St. Jude's internal investigation when market growth slowed and other companies regained market share. The forward-looking warnings predicted events and risks which actually materialized.

b. Misrepresentation

Plaintiffs' amended complaint alleges St. Jude's 2005 fourth quarter earnings report and 2006 first quarter guidance constituted false and misleading statements. According to plaintiffs, St. Jude failed to reveal its channel stuffing in those reports. (Am. Compl. ¶¶ 55, 60, 64, 66). As noted above, however, plaintiffs have walked away from this theory, and their response to defendants'

motion for summary judgment is silent on these points. Where plaintiffs offer no evidence to support this theory, their claim cannot stand.

Discovery revealed no channel stuffing during 2005's fourth quarter. The evidence demonstrated that any bulk purchase discounts and credit terms remained within normal ranges. (Hendrick Aff. ¶ 4.) St. Jude did not buy back any unsold ICDs. (Id. ¶ 5.) Even after an audit, the company has not restated 2005's fourth quarter sales results. (Zurbay Aff. ¶ 2.) The plaintiffs apparently concede these points. As the channel stuffing "fraud" claim has no support, defendants were not obligated to report it for the fourth quarter 2005.

Plaintiffs still claim St. Jude's 2006 first quarter guidance is actionable because it was "made without a reasonable basis." See In re: NationsMart Corp. Sec. Litig., 130 F.3d 309, 320 (8th Cir. 1997). Defendants counter, arguing their estimates were based on a "good faith assumption" that the 2006 ICD market would continue to expand at 15 to 20 percent. (Defs.' Mem. Supp. Summ. J. 22.) They claim a company's error in predicting sales, absent more, does not establish fraud. The Court agrees.

Plaintiffs offer no evidence showing St. Jude knew or recklessly disregarded contrary information when making its first quarter 2006 sales guidance statements. Plaintiffs zealously argue defendants' forecasting process was "inherently unreliable," but

such an assertion does not amount to fraud.[2] Defendants sell medical devices, they are not economic forecasters. While one can argue a company can improve earnings forecasts by including more data, hiring more analysts, or outsourcing the number crunching, the law does not require they do so. See Santa Fe Indus., Inc. v. Green, 430 U.S. 462, 472 (1977) ("[A] cause of action under Rule 10b-5 does not lie for mere negligence."). St. Jude's forecast model had previously yielded accurate results, and the company had used a substantially similar bulk sales methodology since 2003. (Hendrick Aff. ¶ 3.) Here, where plaintiffs have abandoned their allegations of channel stuffing, they have failed to demonstrate defendants intentionally, or even recklessly, mislead the market in its forecast.

2. Scienter

A plaintiff who would avoid summary judgment must show defendants acted with the requisite scienter, and acted intentionally or with a reckless disregard for the truth of a material statement. Kushner v. Beverly Enters., Inc., 317 F.3d 820, 827-31 (8th Cir. 2003). Recklessness can be demonstrated by showing "highly unreasonable omissions or misrepresentations" involving "an extreme departure from the standards of ordinary care . . . presenting a danger of misleading buyers or sellers which is

[2] The Court cannot help but recall the adage which posits "predictions are always difficult, especially about the future."

either known to the defendant or is so obvious that the defendant must have been aware of it." In re: K-Tel Int'l, Inc., Sec. Litig., 300 F.3d 881, 893-94 (8th Cir. 2002) (quotations omitted).

In the case of a forward-looking misstatement, a plaintiff must prove the forward-looking statement was "made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(B)(i). Evidence of motive and opportunity are relevant when establishing scienter. In re: K-Tel Int'l, Inc., Sec. Litig., 300 F.3d at 893-94. Here, the Court holds plaintiffs have failed to raise a genuine and triable issue of material fact as to defendants' intentional, knowing, or reckless behavior.

Citing positive remarks issued by St. Jude representatives on January 25, 2006, February 10, 2006, and March 7, 2006, plaintiffs contend these statements were misleading where defendants knew, but failed to disclose or recklessly disregarded, the company would not meet sales goals where it "engaged in the practice of stuffing its retail" channels with inventory. (Am. Compl. ¶ 64.) Again, however, plaintiffs' memorandum fails to proffer any evidence that defendants knew they engaged in channel stuffing.

Plaintiffs are reduced to asserting that key St. Jude employees "knew facts or had access to information" indicating ICD sales were lagging, yet they did not update the market. See Fla. State Bd. of Admin. v. Green Tree Fin. Corp., 270 F.3d 645, 665 (8th Cir.

2001). Plaintiffs argue such statements demonstrate scienter. (Pls.' Mem. Opp. Summ. J. 42.) Plaintiffs' argument, however, is fatally flawed: they are now arguing defendants possess scienter for a fraud which they have not pled. This brings the Court back to the fact that plaintiffs pled a channel stuffing theory of fraud, sustained that theory in the face of a PSLRA and Rule 12 challenge, and have now abandoned that theory in favor of another which, to date, has not been fully articulated, let alone pled.

3. Individual Liability

Finally, where the Court finds no liability against St. Jude, the Court dismisses the amended complaint against the individual defendants. See Parnes, 122 F.3d at 550 n.10 ("Because the Plaintiffs presented no actionable claim for violation of [Section 10(b), or Rule 10b-5] the claims for controlling person liability were also properly dismissed.").

## III. Conclusion

Plaintiffs placed before this Court an amended complaint accusing defendants of illegally stuffing market channels with its ICD product, thus cannibalizing future sales. Having rung that bell, plaintiffs ask the Court to turn tone deaf. Plaintiffs now accuse defendants of failing to provide timely market updates. This Court will not allow plaintiffs to first, abandon their PSLRA and Rule 12-tested theory of the case; and, at this late date, substitute an untested theory of their choosing. To do so would defeat Congress's expressed intention in enacting the PSLRA and

prejudice defendants.

Accordingly, IT IS ORDERED that Defendants' motion for summary judgment is granted [Docket No. 180].

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: June 22, 2009

s/ James M. Rosenbaum
JAMES M. ROSENBAUM
United States District Judge