NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE ABLE LABORATORIES SECURITIES LITIGATION	Civil Action No. 05-2681 (JAG) **OPINION**

GREENAWAY, JR., U.S.D.J.

This matter comes before this Court on three motions to dismiss the amended complaint, pursuant to FED. R. CIV. P. 12(b)(6). The three motions were filed by defendants Shashikant Shah ("Shah") (motion #1); Garth Boehm ("Boehm") and Robert J. Mauro ("Mauro") (motion #2); and Iva Klemick ("Klemick") and Dhananjay G. Wadekar ("Wadekar") (motion #3) (collectively, "Defendants"). For the reasons set forth below, the motions will be denied.

I. Background

Between May 23, 2005 and June 16, 2005, nine cases[1] were filed in this Court alleging securities fraud violations by Able Laboratories[2] ("Able Labs" or "Able") and various officers of Able. After evaluating seven motions seeking appointment as lead plaintiff (Docket Entry Nos.

[1] By order dated January 25, 2006, these nine cases were consolidated (Docket Entry No. 46).

[2] Able Laboratories was a New Jersey-based company engaged in the development, manufacture, and sale of generic drugs in the form of tablets, capsules, suppositories, and liquids. The company was organized in 1988 under the name DynaGen, Inc., and operated under a consent decree from April 8, 1992 to March 20, 2002, due to prior Food and Drug Administration ("FDA") violations. Looking for a fresh start, the company changed its name to Able Laboratories when the consent decree was dissolved. (Consolidated Class Action Compl. ("Am. Compl.") ¶¶ 30-36.)

3, 6, 7, 11, 12, 13, 17), this Court granted the request of the Denver Employees Retirement Plan ("DERP")[3] and Deka International (Ireland) Limited ("Deka")[4] allowing them to combine in order to form the Institutional Investor Group ("IIG" or "Plaintiff") and to serve as lead plaintiff. In re Able Laboratories Sec. Litig., 425 F. Supp. 2d 562 (D.N.J. 2006). Plaintiff filed an amended complaint (hereinafter "Complaint") which, due to the fact that Able filed for bankruptcy,[5] only named several former Able officers as defendants. (Consolidated Class Action Compl. ("Am. Compl.") ¶¶ 11-15.) Those officers, the named defendants on Plaintiff's amended complaint, are Dhanajay Wadekar,[6] Robert J. Mauro,[7] Shashikant Shah,[8] Garth Boehm, Ph.D.,[9]

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[3] DERP is a defined benefit plan which provides retirement benefits to qualified members of the City and County of Denver and Denver Health and Hospital Authority. (Am. Compl. ¶ 8.)

[4] DEKA is a fund management company which directs and controls investments in various securities around the world on behalf of about 600 funds it manages and administers. (Am. Compl. ¶ 9.)

[5] On July 18, 2005, Able filed a petition to reorganize under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of New Jersey, Trenton Division. (Am. Compl. ¶ 7.)

[6] Dhanajay Wadekar held several positions at Able. He was Chairman of the Board from April 2002 until his resignation on May 19, 2005; Chief Executive Officer ("CEO") from October 2001 until his resignation; and Secretary from November 1998 until his resignation. (Am. Compl. ¶ 11.)

[7] Robert J. Mauro held several positions at Able. He was President, Chief Operating Officer, and a Director of Able from April 2004 through the end of the Class Period. He assumed the role of interim CEO after Wadekar's resignation on May 19, 2005. Mauro resigned as President, interim CEO, and a Director on July 7, 2005. (Am. Compl. ¶ 12.)

[8] Shashikant Shah was Vice President of Quality Control and Regulatory for Able from February 2000 until his resignation in December 2004. Shah continued to serve as a Quality Control consultant after his resignation. (Am. Compl. ¶ 13.)

[9] Garth Boehm was Senior Vice President and Chief Scientific Officer of Able from April 2004 through the end of the Class Period. (Am. Compl. ¶ 14.)

and Iva Klemick[10] (collectively, "Defendants"). (Am. Compl. ¶¶ 11-15.)

Plaintiff brought this action on behalf of those who purchased or acquired Able stock between October 30, 2002 and May 18, 2005, inclusive (the "Class Period"), and were damaged as a result of their purchase. (Am. Compl. ¶ 24.) Specifically, the complaint alleges that: (1) defendants Wadekar, Mauro and Shah violated section 10(b) of the Securities Exchange Act and Securities Exchange Commission ("SEC") Rule 10b-5(b) by making misrepresentations and omissions of material fact in connection with the purchase or sale of Able's securities (Am. Compl. Count I); (2) defendants Wadekar and Shah violated SEC rule 10b-5(a) and (c), promulgated under section 10(b) of the Securities Exchange Act, by employing and engaging in a scheme to defraud Plaintiff and other class members (Am. Compl. Count II); (3) defendants Wadekar and Shah violated section 20A of the Securities Exchange Act by selling substantial numbers of shares of Able common stock during the Class Period while in possession of material non-public information (Am. Compl. Count III); (4) defendant Wadekar violated section 18 of the Securities Exchange Act by making statements which were false or misleading on Able's 10-K form in 2003, which was filed with the SEC (Am. Compl. Count IV); and (5) defendants Wadekar, Mauro, Shah, Boehm, and Klemick violated section 20(a) of the Securities Exchange Act by controlling and influencing Able to commit primary violations of the Securities Exchange Act (Am. Compl. Count V).

Throughout the Class Period, Able obtained FDA approvals to manufacture and market various generic drugs, allegedly through falsification of testing data and inaccurate reporting to

[10] Iva Klemick was Director of Regulatory Affairs for Able from January 2000 through April 2005. She was also appointed Vice President of Compliance in April 2005. (Am. Compl. ¶ 15.)

the FDA. The Complaint attempts to demonstrate this, as well as Able's poor management, by using statements from five confidential witnesses ("CW1-CW5"), all former Able Labs employees,[11] (Am. Compl. ¶¶ 165-75), as well as findings from the FDA Form 483,[12] dated July 1, 2005, and amended July 6, 2005.[13] (Am. Compl. ¶¶ 57-70.) These statements reveal situations in which these witnesses were instructed to falsify or conceal certain data, or in which

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[11] CW1 is a former Quality Control Laboratory Instrumentation Supervisor who worked at Able from 2003 to October 2005. (Am. Compl. ¶ 19.) CW2 is a former Quality Compliance Auditor and Documentation Control Analyst who worked at Able from August 2000 to June 2005. (Am. Compl. ¶ 20.) CW3 is a former Quality Assurance Inspector who worked at Able in 2001. (Am. Compl. ¶ 21.) CW4 is a former Senior Analytical Chemist and Supervisor who worked at Able from 1997 to December 2004. (Am. Compl. ¶ 22.) CW5 is a former Compliance Supervisor in Quality Control who worked at Able from January 2003 to June 2005. (Am. Compl. ¶ 23.)

[12] "After inspecting a food, drug, medical device, or biologic establishment, FDA prepares a written report of its inspection findings, following a debriefing. This report is intended primarily for internal FDA use and is not provided to the inspected institution at the conclusion of the on-site visit. To provide the facility with its own written list of discrepancies noted during the inspection, FDA developed FDA 483, 'Notice of Inspectional Observations,' issued by the field investigator. Form 483 should contain only those observations that can be directly linked to a violation of regulations – not suggestions, guidance, or other comments. Although the 483 does not contain references to the regulations, each observation should be directly traceable to a section of the applicable regulations." Paul W. Goebel, Matthew D. Whalen & Felix Kin-Maung-Gyi, What a Form 483 Really Means, Applied Clinical Trials (Sept. 1, 2001), available at http://www.actmagazine.com/appliedclinicaltrials/ (follow "Archives" hyperlink; then follow "More" hyperlink to September 2001 issue).

[13] Although the Complaint references findings from the FDA Form 483 issued in 2005 after the end of the Class Period, the findings refer to events and conditions, including the falsification of data, that existed during the Class Period, and can be relied upon by Plaintiff in support of its allegations. In re Merck & Co. Sec. Litig., 432 F.3d 261, 271-72 (3d Cir. 2005) ("both post-class-period data and pre-class-period data could be used to 'confirm what a defendant should have known during the class period,' [since] '[a]ny information that sheds light on whether class period statements were false or materially misleading is relevant'" (quoting In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 72 (2d Cir. 2001))).

certain protocols were not followed.[14] (Am. Compl. ¶¶ 165-75.) For example, CW1 claims that soon after Shah's departure, David Chesbro, Associate Director of Quality Control, reported wide discrepancies to Boehm between the data maintained on Able's computer records and the data disclosed to the FDA. (Am. Compl. ¶ 129.) CW2 contends that, by March of 2005, Able's management had distributed a letter to all staff about the retention of outside auditors to review the company's quality control records. (Am. Compl. ¶ 133.) CW3 says that she was told by managers to change data reports and labels in order to conform to the accepted range based on FDA requirements. (Am. Compl. ¶ 165.) CW4 alleges that Able, in 2003, began hiring inadequately trained chemists from India, and that Wadekar personally recruited them. (Am. Compl. ¶ 169.) Finally, CW5 states that the Quality Control Lab Managers, whose duty it was to review test results and conduct random reviews, rarely, performed the supervisory tasks charged to them. (Am. Compl. ¶ 170.)

The Complaint further attempts to demonstrate Able's flagrant FDA violations by contending that, on April 19, 2004, during the Class Period, Able received a warning letter from the FDA regarding the results of the FDA's January - February 2004 inspection. (Am. Compl. ¶ 55.) The letter, addressed to Wadekar, stated that "[t]he specific violations noted in this letter

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[14] Plaintiff has satisfied the Third Circuit standard for relying on confidential sources to meet the particularized pleading burden of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). Cal. Pub. Employees Ret. Sys. v. Chubb Corp., 394 F.3d 126, 147- 48 (3d Cir. 2004) (hereinafter ("CALPERS") (adopting the Second Circuit standard that there is no obligation to name the confidential source, as long as the confidential source is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged"). See also In re Royal Dutch/Shell Transp. Sec. Litig., No. 04-CV-347 (JAP), 2006 U.S. Dist. WL 2355402, at *7 (D.N.J. Aug. 14, 2006) (applying the CALPERS reasoning regarding the use of confidential sources to Rule 10b-5(a) and (c) claims). The Complaint adequately describes the position of each confidential source. (Am. Compl. ¶¶ 18-23.)

are serious and may be symptomatic of serious underlying problems. You are responsible for investigating and determining the causes of the violations identified above and preventing recurrence of similar violations." (Id.) The letter from the FDA was revealed to investors in Able's Form 10-Q for the first quarter of 2004, which Able filed with the SEC on May 7, 2004. (Am. Compl. ¶ 103.)

On July 6, 2005, six weeks after the end of the Class Period, the FDA issued a Form 483 to Able, outlining twelve observations regarding deficiencies in Able's quality control system, which allegedly existed during the Class Period: (1) Able's quality control unit lacked authority to investigate fully errors that occurred (Am. Compl. ¶ 58); (2) Able failed to reject drug products which should have been rejected due to failure to meet established standards, specifications, and quality control criteria (Am. Compl. ¶¶ 59-60); (3) Able failed to disclose adverse information in post-approval reports submitted to the FDA (Am. Compl. ¶ 61); (4) "[a]n [abbreviated new drug application ("ANDA")[15]] [A]NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application" (Am. Compl. ¶ 62); (5) Able failed to include in its laboratory records complete data derived from all tests necessary to assure compliance with established specifications and standards (Am. Compl. ¶ 63); (6) Able did not check the input and output from computers and other records for accuracy (Am. Compl. ¶ 64);

[15] According to the FDA, "[a]n Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public." U.S. Food and Drug Administration, Center for Drug Evaluation Research, Drug Applications, Abbreviated New Drug Application (ANDA) Process for Generic Drugs, www.fda.gov/cder/regulatory/applications/ANDA.htm.

(7) Able did not make written records of "investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications" (Am. Compl. ¶ 65); (8) "[e]mployees are not given training in current good manufacturing practices and written procedures required by current good manufacturing practices regulations" (Am. Compl. ¶ 66); (9) when Able did prepare written records of investigations into unexplained discrepancies, those reports did not always include the conclusions and follow-up (Am. Compl. ¶ 67); (10) the responsibilities and procedures applicable to the quality control unit were not in writing and were not followed fully (Am. Compl. ¶ 68); (11) Able did not follow established laboratory control mechanisms (Am. Compl. ¶ 69); and (12) Able had not established control procedures "which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product" (Am. Compl. ¶ 70).

The July 2005 Form 483 was issued by the FDA after the Class Period, but Plaintiff alleges that Defendants concealed their egregious violations during the entirety of the Class Period in order to "eclipse Wall Street's expectations." (Am. Compl. ¶ 71.) Therefore, Plaintiff alleges that Defendants' intentional concealment of their continuing FDA violations and reassurance that FDA standards were being complied with, in statements appearing on SEC forms, in press releases, and in conferences with analysts, caused Plaintiff (and others similarly situated) to suffer significant losses when Defendants' conduct was revealed and the price of Able's stock collapsed. (Am. Compl. ¶ 3.)

II. Facts

The Complaint alleges several instances in which Defendants provided material misstatements or omissions in violation of the Securities Exchange Act of 1934.[16] On March 20, 2002, Able "'hired individuals who were knowledgeable and committed to [the FDA's current Good Manufacturing Practices ("cGMP")] compliance, and instituted operational procedures that enforce cGMP compliance.'" (Am. Compl. ¶ 36 (quoting Press Release, Able Laboratories, Inc. (March 20, 2002)).) In addition, Wadekar stated "we are extremely pleased to have the consent decree dissolved." (Am. Compl. ¶ 36.) The Class Period subsequently began on October 30, 2002. On the same day, Able issued a press release titled "Able Laboratories Reports 2002 Third Quarter Results." The company stated that "in October 2002, the Company received three ANDA approvals and currently has 17 ANDAs pending approval by the FDA." (Am. Compl. ¶ 72.)

On November 13, 2002, Able filed SEC Form 10-Q which stated that, during the quarter ending September 30, 2002, "the Company had 15 FDA-approved product families in 25 different strengths available for sale, compared to 12 FDA-approved product families in 21 different strengths in the prior quarter." (Am. Compl. ¶ 74.) The 10-Q Form also "stated that Able had received FDA approval for three new products during the third quarter and three additional products in October 2002, and had 20 new products pending FDA approval." (Id.) The Form 10-Q was signed by, and included a certification from, Wadekar. (Id.)

On December 10, 2002, Wadekar commented on Able's performance during a CCBN

[16] Events that occurred both before and after the Class Period are included in the Complaint and are therefore included in this timeline.

Virtual Healthcare Conference, stating that "'our growth has been driven by approximately 22 FDA approvals we [have] received since the year 2001. . . . Our facility is fully compliant with the current good manufacturing practices.'" (Am. Compl. ¶ 76.)

On March 5, 2003, Able issued a press release titled "Able Laboratories Reports Record Sales of $52.9 million for 2002," which quoted Wadekar as observing that "'we believe 2003 will be an overall up year for the Company.'" (Am. Compl. ¶ 78 (internal citation omitted).)

On March 25, 2003, Able filed SEC Form 10-K, which contained their annual report for 2002 and "represented that Able was in compliance with all FDA manufacturing regulations." (Am. Compl. ¶ 79.) "'We use biostudies to demonstrate that the rate and extent of absorption of a generic drug are not significantly different from that achieved by the corresponding brand-name drug. These biostudies are subject to rigorous standards set by the FDA.'" (Am. Compl. ¶ 79 (quoting Able Laboratories, Inc., Annual Report (Form 10-K) (Mar. 25, 2003)).) Able further stated "we do not expect the [Generic Drug Enforcement Act of 1992[17]] to have a material impact on the review or approval of our ANDAs." (Id.) As had been done earlier, this form was certified by defendant Wadekar. (Am. Compl. ¶ 79.)

On May 6, 2003, Able issued a press release titled "Able Laboratories Reports First Quarter 2003 Results," which stated that "'[o]ur fundamentals and pipeline continue to be strong as we are awaiting approvals on several additional promising ANDAs.'" (Am. Compl. ¶ 83

[17] The Generic Drug Enforcement Act of 1992 "authorizes the FDA to permanently or temporarily bar companies . . . from submitting or assisting in the submission of an ANDA. The FDA may also temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and . . . [can] withdraw approval of an ANDA and . . . seek civil penalties." (Am. Compl. ¶ 79.)

(quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports First Quarter 2003 Results (May 6, 2003)).)

On May 14, 2003, Able filed SEC Form 10-Q, which stated that it had received FDA approvals for four new products during the quarter and two additional products in April 2003. It also stated that it had thirteen more products pending FDA approval. This Form was also certified by defendant Wadekar. (Am. Compl. ¶ 84.)

On July 28, 2003, Able issued a press release titled "Able Laboratories Reports Record Second Quarter 2003 Results," which stated "'[t]he Company received 5 [ANDA] approvals during the second quarter of 2003 and currently has 11 ANDAs pending approval by the [FDA] representing approximately $300 million in total market size. In addition, the Company has 23 projects currently under development addressing a total market of approximately $2.9 billion.'" (Am. Compl. ¶ 86 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Record Second Quarter 2003 Results (July 28, 2003)).) Wadekar added that "[o]ur fundamentals and pipeline continue to be strong as we are pursuing approval of several additional ANDAs." (Id.) On the same day, during a conference call with analysts, Wadekar commented on Able's performance by stating "'[w]e completed our last phase of construction at the end of first quarter, which increased our manufacturing, R&D, as well as quality control capacity.'" (Am. Compl. ¶ 87 (quoting Able Laboratories, Inc. Teleconference July 28, 2003).)

On November 4, 2003, Able issued a press release titled "Able Laboratories Reports Third Quarter 2003 Results," which stated that "'[t]he company received 2 [ANDA] approvals, during the third quarter of 2003, and currently has 17 ANDAs pending approval by the [FDA] representing approximately $400 million in total market opportunity. In addition, the Company

has over 20 projects currently under development addressing a total generic and branded market of approximately $1 billion.'" (Am. Compl. ¶ 91 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Third Quarter 2003 Results (Nov. 4, 2003)).) Wadekar touted Able's progress by emphasizing "'the growth in ANDA's [sic] pending with the FDA from 11 last quarter at this time to 17 currently.'" (Id.)

On November 14, 2003, Able filed SEC Form 10-Q, which stated that Able "'had received FDA approval for three new products during the quarter and has 17 ANDAs still pending approval.'" (Am. Compl. ¶ 92 (quoting Able Laboratories, Inc., Quarterly Report (Form 10-Q) (Nov. 14, 2003)).) As before, this Form was certified by defendant Wadekar. (Id.)

On February 26, 2004, Able issued a press release titled "Able Laboratories Reports Record Sales and Operating Income for 2003," which stated that "'[t]he increase over the prior year primarily results from additional research and related bio-studies conducted to further develop the Company's product pipeline. . . . The Company received 13 ANDA approvals during 2003 versus 10 for 2002 and filed 13 new ANDAs in 2003.'" (Am. Compl. ¶ 94 (quoting Press Release, Able Laboratories, Inc., "Able Laboratories Reports Record sales and Operating Income For 2003" (Feb. 26, 2004)).) Defendant Wadekar commented that "'[o]ur 2003 results were driven primarily by our 13 ANDA approvals and market penetration into certain key accounts.'" (Id.) On the same day, during an earnings conference call, Wadekar stated "we're expecting about 10 to 12 ANDAs in 2004. . . . [W]e're looking at about two to four in the first half of this year and the remainder coming in the latter part. The growth in sales is expected to come from the approval as we anticipate steady core business with flat to slightly declining pricing for the existing products.'" (Am. Compl. ¶ 95 (quoting Able Laboratories, Inc.

Teleconference, Feb. 26, 2004).)

On March 15, 2004, Able filed SEC Form 10-K, containing its annual report for 2003, which stated "'we believe we are currently in compliance with all applicable FDA requirements' and '[w]e do not expect the [Generic Drug Enforcement Act of 1992] to have a material impact on the review or approval of our ANDAs.'" (Am. Compl. ¶ 96 (quoting Able Laboratories, Inc., Annual Report (Form 10-K) (Mar. 15, 2004)).) This Form was certified by defendant Wadekar. (Id.)

On April 26, 2004, Able issued a press release titled "Able Laboratories Reports First Quarter 2004 Results," which stated that "'[t]he Company received one [ANDA] approval during the first quarter of 2004 and currently has 18 ANDAs pending approval by the [FDA] addressing a total market size of approximately $630 million.'" (Am. Compl. ¶ 100 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports First Quarter 2004 Results (April 26, 2004)).) Defendant Wadekar added that "'[w]e anticipate several product approvals over the next 4-6 months, one of which could be a first-to-market product. We currently have 18 ANDAs on file with the FDA and anticipate filing additional ANDAs, for solid dose and liquids [sic] products, throughout the year.'" (Id.)

On May 7, 2004, Able filed SEC Form 10-Q, which stated that research and development costs had increased due to "'increased activity in supporting a higher number of research projects . . . includ[ing] quality assurance, stability testing and regulatory support.'" (Am. Compl. ¶ 102 (quoting Able Laboratories, Inc., Quarterly Report (Form 10-Q) (May 7, 2004)).) This Form also disclosed that the FDA had initiated an inspection of the South Plainfield Facility in January of 2004 and had issued a warning letter to Wadekar. (Am. Compl. ¶ 103.) Regarding the warning

letter, Able said, in the Form 10-Q, "'we believe that the warning letter may not materially affect our operations.'" (Id.) Defendant Wadekar certified this form. (Id.)

On July 27, 2004, Able issued a press release titled "Able Laboratories Reports Second Quarter 2004 Results," which stated that Able "'received five [ANDA] approvals during the second quarter, with one approval received during the first quarter and four additional approvals during July 2004. The company currently had nine ANDAs pending approval by the [FDA] addressing a total market size of approximately $400 million.'" (Am. Compl. ¶ 105 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Second Quarter 2004 Results (July 27, 2004)).) Wadekar commented that "'[w]e anticipate several additional product approvals over the next few months in addition to the 10 approvals received to date in 2004. We currently have nine ANDAs on file with the FDA and anticipate filing additional ANDAs . . . throughout the remainder of the year.'" (Id.)

On August 6, 2004, Able filed SEC Form 10-Q, which stated that "the Company had received FDA approval for six new products during the quarter and thirteen more in July 2004, and that it had four ANDAs still pending approval." (Am. Compl. ¶ 106.) The Company further stated "'[w]e expect to be able to address the FDA's observations in a timely and effective manner, and we believe the warning letter may not materially affect our operations. Since receiving the warning letter, we have received 14 new ANDA approvals.'" (Id. (quoting Able Laboratories, Inc., Quarterly Report (Form 10-Q) (Aug. 6, 2004)).) This Form was certified by defendant Wadekar. (Id.)

On November 2, 2004, Able issued a press release titled "Able Laboratories Reports Third Quarter 2004 Results, Able Achieves Record Sales, Operating Income and Earnings Per

Share," which stated that "'[t]he Company received 10 [ANDA] approvals during the third quarter. The Company currently has five ANDAs pending approval by the [FDA] addressing a total market size of approximately $300 million.'" (Am. Compl. ¶ 109 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Third Quarter 2004 Results (Nov. 2, 2004)).) Wadekar commented that "'[w]e anticipate additional product approvals over the next few months in addition to the 16 approvals received to date in 2004. We currently have five ANDAs on file with the FDA and anticipate filing between 15 and 20 additional ANDAs during the remainder of the year and through the first half of 2005.'" (Id.)

On November 9, 2004, Able filed SEC Form 10-Q, which stated that Able had "28 FDA-approved product families, in 73 different strengths, compared to 21 product families in 47 different strengths as of September 30, 2003." (Am. Compl. ¶ 110.) The Form 10-Q further stated that "'[i]n 2004, we expect to continue to increase our sales of generic drug products by attempting to increase sales of our existing products and by obtaining [ANDA] approvals from the FDA for new products.'" (Id. (quoting Able Laboratories, Inc., Quarterly Report (Form 10-Q) (Nov. 9, 2004)).) The 10-Q Form noted that Able had five ANDAs pending approval and expected to file fifteen to twenty more over the next several months. (Id.) It also stated that the Company was up to approximately 59 quality and regulatory employees. (Id.) Finally, the Form repeated its prior assurances regarding the FDA's warning letter. (Id.) The Form was certified by Wadekar. (Id.)

On December 31, 2004, Shah formally resigned as Vice President of Quality and Regulatory at Able to take on a new role in Quality Control. (Am. Compl. ¶ 128.) Able filed SEC Form 8-K, which stated that Able "'entered into an amendment to the employment

agreement between the Company and Shashikant C. Shah, the Company's Vice President of Quality and Regulatory, in connection with Mr. Shah's transition to the position of Quality Control Consultant.'" (Id. (quoting Able Laboratories, Inc., Current Event (Form 8-K) (Jan. 3, 2005)).) Within a week, Able initiated its first recall since 2001. (Am. Compl. ¶ 131.)

On February 11, 2005, Able initiated a nationwide recall of over 2 million units of Promethazine Hydrochloride suppositories, an antihistamine, due to stability failure. (Am. Compl. ¶ 132.)

On March 7, 2005, Able issued a press release titled "Able Laboratories Reports Financial Results for 2004, Fourth Quarter and Full Year," which stated that "'[t]he Company currently has six ANDAs pending approval by the [FDA] addressing a total market size of approximately $500 million. In addition, the Company has 18 projects currently under development addressing a total market size of approximately $2.6 billion.'" (Am. Compl. ¶ 112 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Financial Results for 2004, Fourth Quarter and Full Year (Mar. 7, 2005)).) The press release also stated that "'[t]he Company received FDA approval for 16 new products during 2004.'" (Id.) Wadekar commented that "'[w]e achieved record sales and earnings in the fourth quarter and for the year. Supported by our 16 ANDA approvals in 2004, we have also seen increased acceptance of our products by several key customers as a result of the efforts of our sales management team.'" (Am. Compl. ¶ 113 (quoting Press Release, Able Laboratories, Inc., Able Laboratories Reports Financial Results for 2004, Fourth Quarter and Full Year (Mar. 7, 2005)).)

On March 15, 2005, Able filed SEC Form 10-K, containing its annual report for 2004, which stated that Able had 16 new products pending approval by the FDA and that it had forty

quality and regulatory employees devoted to providing support for the primary research and development activity. (Am. Compl. ¶ 114.) This Form also stated that "[w]e believe we are currently in compliance with all applicable FDA requirements . . . [w]e do not expect the law to have a material impact on the review or approval of our ANDAs." (Am. Compl. ¶ 115 (quoting Able Laboratories, Inc., Annual Report (Form 10-K) (Mar. 15, 2005)).) Regarding the FDA's warning letter of April 2004, the Form 10-K stated that "[w]e believe that we have responded to the FDA's observations in a timely and effective manner and do not expect this event to materially affect our operations." (Am. Compl. ¶ 116.) The 10-K Form identified forty-four FDA-approved drugs, nine of which would later be found by the FDA to have been approved through violations of cGMPs. (Am. Compl. ¶ 117.) The Form was signed by Wadekar and Mauro. (Am. Compl. ¶ 114.)

On April 5, 2005, Able initiated a nationwide recall of approximately 29,000 packages of an anti-nausea medication due to "impurity failures." (Am. Compl. ¶ 134.) Able also initiated a Florida and Ohio recall of 3,034 packages of a beta blocker due to instability. (Id.)

On May 2, 2005, the FDA began an inspection of Able's quality controls and found numerous instances of egregious misconduct, which would ultimately be reflected in its Form 483. (Am. Compl. ¶ 135.)

On May 5, 2005, Able issued a press release titled "Able Laboratories Reports Financial Results for First Quarter 2005," which stated that "'[t]he Company currently has six ANDAs pending approval by the [FDA] addressing a total market size of approximately $500 million. In addition, the Company has approximately 15 projects currently under development addressing a total market size of approximately $2.5 billion.'" (Am. Compl. ¶ 120 (quoting Press Release,

Able Laboratories, Inc., Able Laboratories Reports Financial Results for First Quarter 2005 (May 5, 2005)).)

The next day, on May 6, 2005, in an earnings conference call, Wadekar assured the public of Able's continuing success. (Am. Compl. ¶ 121.) He reported that Able had six ANDAs pending with the FDA with a market size of approximately $500 million and that it expected to file fifteen more in 2005 with total sales of $2.5 billion. (Id.) An analyst asked Wadekar what impact the recall of Promethazine suppositories, which had occurred in February of that year, had had on Able. (Am. Compl. ¶ 122.) Defendant Wadekar responded that the impact was fairly contained and the recall would have no impact on the second quarter. (Id.) Able stock closed at $25.59, which was 6.2% higher than its close on the previous day of $24.09. (Am. Compl. ¶ 123.) Able's stock price reached an all-time high closing price of $25.65 three days later, on May 9, 2005. (Id.)

On May 10, 2005, Able filed SEC Form 10-Q, which stated that "'[d]uring the quarter ended March 31, 2005, we conducted voluntary product recalls affecting three product families for noncompliance with labeling requirements . . . and . . . stability failure. Recently we also decided to recall one batch . . . for improper laboratory practices and noncompliance with standard operating procedures. . . . [W]e have initiated a thorough internal evaluation of our operating practices with the knowledge of the FDA. . . . [W]e have created a new executive officer position, Vice President, Compliance, and promoted Iva Klemick, our former Director of Regulatory Affairs, to serve in this position. . . . We have also retained the services of a highly reputable outside consulting firm to assist us in this initiative.'" (Am. Compl. ¶ 124 (quoting Able Laboratories, Inc., Quarterly Report (Form 10-Q) (May 10, 2005)).) This Form was

certified by defendant Wadekar. (Am. Compl. ¶ 126.)

Able's stock price for the next several days "hovered at its all-time high." (Am. Compl. ¶ 125.) On May 18, 2005, the last day of the Class Period, Able's stock reached its all-time trading high of $26.49, closing that day at $26.43. (Am. Compl. ¶ 136.)

On May 19, 2005, Able issued a press release titled "Able Laboratories, Inc. Updates Status of Internal Review, Withdraws Guidance," in which it stated that "'the Company has identified apparent departures from standard operating procedures with respect to certain laboratory testing practices. As a result of these observations, the Company will be recalling additional products in the future. . . . This disruption in shipment . . . is expected to have a material effect on the Company's ability to meet its sales goals and operating objectives. Therefore, the Company is withdrawing its prior guidance as to its financial performance.'" (Am. Compl. ¶ 137 (quoting Press Release, Able Laboratories Inc., Able Laboratories, Inc. Updates Status of Internal Review, Withdraws Guidance (May 19, 2005)).) Two hours later, Able announced the resignation of Wadekar. (Am. Compl. ¶ 138.) Able also announced that Mauro would assume the role of interim Chief Executive Officer. (Id.) Able's share price collapsed 75% from its previous day close of $24.63 to close at $6.26. (Id.)

On May 23, 2005, Able issued a press release titled "Able Laboratories, Inc. Suspends Manufacturing Operations, Announces Product Recall - To Withdraw Certain Abbreviated New Drug Applications," in which it announced that the quality control problems with its products were so severe that it was recalling all of its products and would withdraw previously approved ANDAs. (Am. Compl. ¶ 139.) Able's stock price closed at $5.05. (Am. Compl. ¶ 140.)

On May 27, 2005, Able announced that it was laying off 200 people because of its

suspension of manufacturing activities. (Am. Compl. ¶ 141.)

On July 7, 2005, Able announced Mauro's resignation as President, interim Chief Executive Officer, and director. (Am. Compl. ¶ 143.) The next day, on July 8, 2005, Able announced that it had received the Form 483 from the FDA. (Am. Compl. ¶ 144.) Able's stock price closed at $2.88. (Id.)

On July 18, 2005, Able filed a petition to reorganize under Chapter 11 of the Bankruptcy Code. (Am. Compl. ¶ 148.) Four days later, on July 22, 2005, Able announced that it had received notice that its securities would be de-listed from the NASDAQ. (Am. Compl. ¶ 149.)

Finally, on August 15, 2005, Able issued a press release stating that it "'now believes that as a practical matter it will not be able to return any of its products to [the] market. . . . Able has determined that the best course of action to preserve value for its creditors and others would be to immediately reduce overhead and expenses as much as possible and to initiate the process of selling the company's business and assets to one or more third-party purchasers rather than attempting to obtain financing to permit it to resume manufacturing and marketing on its own. . . . Accordingly, in Able's view, it is not likely that the common stock has any value.'" (Am. Compl. ¶ 151 (quoting Press Release, Able Laboratories, Inc. (Aug. 15, 2005)).)

III. Stock transactions

The numerous stock sales made by defendants Wadekar and Shah are set forth in paragraph 185 of the Complaint and will not be recounted here in their entirety. (Am. Compl. ¶ 185.) As to the named plaintiff's transactions, Deka's transactions are set forth in the certification attached as Exhibit C to the Declaration of Christopher S. Hinton in Support of the Motion of Deka Ireland for Consolidation, Appointment as Lead Plaintiff and Approval of Lead

Plaintiff's Selection of Lead Counsel. (Docket Entry No. 13.) DERP also purchased stock on various dates, as set forth in the certification attached as Exhibit A to the Declaration of Stuart M. Grant in Support of the Denver Employees Retirement Plan's Motion for Consolidation and the Appointment of Lead Plaintiff and for Approval of its Selection of Counsel. (Docket Entry No. 5.)

IV. Legal Discussion

A. FED. R. CIV. P. (12)(b)(6)

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the claim is and the grounds upon which it rests.'" Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1964 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957), while abrogating the decision in other respects). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Twombly, 127 S. Ct. at 1964-65. "Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." Id. at1965.

Under Federal Rule of Civil Procedure 12(b)(6), a motion to dismiss should be granted if the plaintiff is unable to articulate "enough facts to state a claim to relief that is plausible on its face." Twombly, 127 S. Ct. at 1974 (abrogating Conley, 355 U.S. 41). A complaint should be dismissed only if the alleged facts, taken as true, fail to state a claim. See In re Warfarin Sodium, 214 F.3d 395, 397-98 (3d Cir. 2000).

On a motion to dismiss for failure to state a claim, pursuant to FED. R. CIV. P. 12(b)(6), the court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party. See Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384-85 (3d Cir. 1994).

While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. See Morse v. Lower Merion School District, 132 F.3d 902, 906 n.8 (3d Cir. 1997). All reasonable inferences, however, must be drawn in the plaintiff's favor. See Sturm v. Clark, 835 F.2d 1009, 1011 (3d Cir. 1987). Moreover, the claimant must set forth sufficient information to outline the elements of his or her claims or to permit inferences to be drawn that the elements exist. See FED. R. CIV. P. 8(a)(2); Conley v. Gibson, 355 U.S. 41, 45-46, abrogated on other grounds. "The defendant bears the burden of showing that no claim has been presented." Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

The court may consider the allegations of the complaint, as well as documents attached to or specifically referenced in the complaint, and matters of public record. See City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998); 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1357 (2d ed. 1990). "Plaintiffs cannot prevent a court from looking at the texts of the documents on which its [sic] claim is based by failing to attach or explicitly cite them." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997). "A 'document integral to or explicitly relied on in the complaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" Id. (citation omitted). Any further expansion beyond the pleading, however, may require conversion of the

motion into one for summary judgment. FED. R. CIV. P. 12(b).

"[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document. Otherwise, a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). Consideration of these referenced documents will not require the conversion of a motion to dismiss to one for summary judgment under FED. R. CIV. P. 12(b)(6). "The reason that a court must convert a motion to dismiss to a summary judgment motion if it considers extraneous evidence submitted by the defense is to afford the plaintiff an opportunity to respond. When a complaint relies on a document, however, the plaintiff obviously is on notice of the contents of the document, and the need for a chance to refute evidence is greatly diminished." Id. at 1196-97. Even if a "[c]omplaint does not *explicitly* refer to or cite [a document] . . . the language in both Shaw and Trump makes clear that what is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." Burlington Coat, 114 F.3d at 1426 (emphasis in original) (citing Shaw v. Digital Equip. Corp., 82 F.3d 1194 (1st Cir. 1996) and In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357 (3d Cir. 1993)).

B. FED. R. CIV. P. 9(b)

In pleading fraud, FED. R. CIV. P. 9(b) establishes a heightened pleading standard by requiring that "the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." "Rule 9(b)'s heightened pleading standard gives defendants notice of the claims against them,

provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." Burlington Coat, 114 F.3d at 1418 (citations omitted). Rule 9(b) "requires plaintiffs to plead 'the who, what, when, where, and how: the first paragraph of any newspaper story.'" In re Advanta Corp. Sec. Litig., 180 F.3d 525, 534 (3d Cir. 1999) (quoting DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990)). "Although Rule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, plaintiffs must use 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002) (quoting In re Nice Sys., 135 F. Supp. 2d 551, 577 (D.N.J. 2001)). "[I]n applying Rule 9(b), courts should be 'sensitive' to situations in which 'sophisticated defrauders' may 'successfully conceal the details of their fraud.'" Id. (quoting Burlington Coat, 114 F.3d at 1418). "Where it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control, the rigid requirements of Rule 9(b) may be relaxed." Id.

C. Section 10(b) of the Securities Exchange Act of 1934

Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), prohibits the use of fraudulent schemes or devices in connection with the purchase or sale of securities. Under § 10(b), it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . , any manipulative or deceptive device or contrivance in contravention" of any rule promulgated by the SEC designed to protect the investing public. To implement the statute, the SEC enacted Rule 10b-5. Any violation of Rule 10b-5 gives rise to a private cause of action. Ernst & Ernst v. Hochfelder, 425 U.S. 185 (1976); Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723 (1975).

That rule, in turn, deems it unlawful:

> (a) [t]o employ any device, scheme, or artifice to defraud,
>
> (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.

17 C.F.R. § 240.l0b-5. The Supreme Court has held that standing to bring a private cause of action under Rule l0b-5 is limited to actual purchasers or sellers of securities. Blue Chip Stamps, 421 U.S. at 749.

1. Rule 10b-5(b) Claims

The majority of securities fraud cases brought under section 10(b) allege that a defendant has made false or misleading statements or omissions of material facts, in violation of Rule 10b-5(b). In re Global Crossing, Ltd. Sec. Litig., 322 F. Supp. 2d 319, 328 (S.D.N.Y. 2004). Rule 10b-5(b), specifically, prohibits the making of an "untrue statement of a material fact or . . . [omission of] . . . a material fact necessary . . . to make the statements made . . . not misleading." 17 C.F.R. § 240.10b-5(b).

To allege a violation under section 10(b) and Rule 10b-5(b), the Supreme Court has recently noted that "[i]n cases involving publicly traded securities and purchases or sales in public securities markets, the action's basic elements include: (1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation'; (5) economic loss; and (6) 'loss

causation,' i.e., a causal connection between the material misrepresentation and the loss." Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341 (2005) (citations omitted). See also In re: Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 275 (3d Cir. 2006).

Rule 9(b) imposes heightened pleading requirements on plaintiffs in Rule 10b-5 actions. "'Rule 9(b) requires a plaintiff to plead (1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage.'" Suprema, 438 F.3d at 276 (quoting In re Rockefeller Ctr. Props., 311 F.3d at 216 (internal quotation marks and citations omitted)).

The Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, further refines this standard by requiring that a complaint which asserts a §10(b) claim "shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Further, if "proof that the defendant acted with a particular state of mind" is a required element of the claim, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). "To the extent that Rule 9(b)'s allowance of general pleading with respect to mental state conflicts with the PSLRA's requirement that plaintiffs state with particularity facts giving rise to a strong inference that the defendant acted with scienter, 15 U.S.C. § 78u-4(b)(2), the PSLRA 'supersedes Rule 9(b) as it relates to Rule 10b-5 actions.'" Suprema, 438 F.3d at 277 (quoting In

re Advanta Corp., 180 F.3d at 531 n.5).

A plaintiff who alleges securities fraud must "allege specific facts that give rise to a 'strong inference' that the defendant possessed the requisite intent." Burlington Coat, 114 F.3d at 1418. "[T]o determine whether a complaint's scienter allegations can survive threshold inspection for sufficiency, a court governed by [15 U.S.C. § 78u-4(b)(2)] must engage in a comparative evaluation; it must consider, not only inferences urged by the plaintiff, . . . but also competing inferences rationally drawn from the facts alleged. An inference of fraudulent intent may be plausible, yet less cogent than other, nonculpable explanations for the defendant's conduct. To qualify as 'strong' within the intendment of [15 U.S.C. § 78u-4(b)(2)], we hold, an inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2504-05 (2007). In making this determination, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss. . . . The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Id. at 2509 (emphasis in original).

A plaintiff may establish this strong inference of scienter "'either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" Suprema, 438 F.3d at 276 (quoting Burlington Coat, 114 F.3d at 1418 (citations omitted)).[18]

[18] In Tellabs, the Supreme Court recently observed that it had "previously reserved the question of whether reckless behavior is sufficient for civil liability under § 10(b) and Rule 10b-5." Tellabs, 127 S.Ct. at 2507 n.3. The Court acknowledged that "[e]very Court of Appeals that

Recklessness, in turn, involves "'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 or is so obvious that the actor must have been aware of it.'" In re Advanta Corp., 180 F.3d at 535 (quoting McLean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)). "[S]cienter may be alleged by stating with particularity facts giving rise to a strong inference of conscious wrongdoing, such as intentional fraud or other deliberate illegal behavior." Id.

Thus, in analyzing the claims set forth in the Complaint, this Court shall apply the pleading requirements established by Rule 10b-5, the heightened pleading requirements imposed by FED. R. CIV. P. 9(b), and the standards established by the PSLRA.

a. Materiality

The materiality claim should be the first step in the analysis. Burlington Coat, 114 F.3d at 1417 ("[T]he first step for a Rule 10b-5 plaintiff is to establish that defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading."). To be material, there must be a "'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information available.'" In re Advanta Corp., 180 F.3d at 538 (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)).

The Third Circuit, in Burlington Coat, "fashioned a special rule for measuring materiality

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has considered the issue has held that a plaintiff may meet the scienter requirement by showing that the defendant acted intentionally or recklessly, though the Circuits differ on the degree of recklessness required." Id. However, the question of recklessness was not at issue in Tellabs, so the Court did not comment on the relative merits of the various Circuits' standards. Id.

in the context of an efficient securities market. [In an efficient securities market,] the price of a company's stock is determined by all available information regarding the company and its business. In such an efficient market, 'information important to reasonable investors . . . is immediately incorporated into the stock price.' As a result, when a stock is traded in an efficient market, the materiality of disclosed information may be measured post hoc by looking at the movement, in the period immediately following disclosure, of the price of the firm's stock. Because in an efficient market 'the concept of materiality translates into information that alters the price of the firm's stock,' if a company's disclosure of information has no effect on stock prices, 'it follows that the information disclosed . . . was immaterial as a matter of law.'" Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quoting Burlington Coat, 114 F.3d at 1425) (internal citations omitted).

In Merck, the Third Circuit noted that, "as compared to the other courts of appeals, [it] ha[d] one of the 'clearest commitments' to the efficient market hypothesis," as exemplified in the Oran-Burlington standard. In re Merck & Co. Sec. Litig., 432 F.3d at 269 (3d Cir. 2005) (internal citations omitted).

Here, Plaintiff alleges that Able's stock was traded on the NASDAQ (Am. Compl. ¶ 37), and that the stock price plunged 75% – from a close of $24.63 on May 18, 2005, to a close of $6.36 on May 19, 2005, the date Able announced suspension of the sale of its products and the resignation of Wadekar (Am. Compl. ¶¶ 137-38). The Complaint also identifies numerous statements made during the Class Period that allegedly were misstatements or omissions of

material facts.[19] Essentially, the Complaint references every form 10-K filed with the SEC during the Class Period, every Form 10-Q filed during the Class Period, various press releases, and statements made during earnings conference calls and other conferences. (Am. Compl. ¶¶

[19] Shah argues that the Complaint does not allege that he signed any forms filed with the SEC, made any statements quoted in any press release, or participated in any conference calls. (Mem. of Law in Supp. of Mot. to Dismiss of Shashikant Shah (hereinafter "Shah Mem. to Dismiss") 1, 4.) Therefore, he concludes that the Complaint fails to allege that he made any statements, whether true or false, that could form the basis for a violation of Rule 10b-5(b). He also argues that, since he did not directly make any statements, and since the Supreme Court's decision in Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164 (1994), eliminated aiding and abetting liability under § 10(b), he cannot be held liable under § 10(b) for any misstatements or omissions made during the Class Period. (Shah Mem. to Dismiss 11-12.) This theory misreads both the statute and the decision in Central Bank. While the Supreme Court concluded "that a private plaintiff may not maintain an aiding and abetting suit under § 10(b)," Central Bank, 511 U.S. at 191, it also recognized that § 10(b) proscribes certain conduct, whether it is engaged in directly or indirectly, id. at 176. Further, "[t]he absence of § 10(b) aiding and abetting liability does not mean that secondary actors in the securities markets are always free from liability under the securities Acts." Id. at 191. The Supreme Court recently reaffirmed this conclusion by noting that "[t]he § 10(b) implied right of action does not extend to aiders and abettors. The conduct of a secondary actor must satisfy each of the elements or preconditions for liability." Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 128 S. Ct. 761, 769 (2008).

The Complaint alleges that Shah was responsible for ensuring "that Able complied with FDA and DEA regulations, filing and receiving FDA approvals for Able's Abbreviated New Drug Application ('ANDA') submissions, and maintaining high quality products. . . . The Company's public statements regarding its quality controls and regulatory compliance during the Class Period, including statements in its SEC filings and press releases, were prepared by or under the direction of Shah." (Am. Compl. ¶ 13.) Further, the Complaint alleges that the false and misleading statements at issue include "statements and omissions in the Company's 2002 Form 10-K, which were prepared by or under the direction of (among others) Wadekar and Shah, . . . statements and omissions in the Company's 2003 Form 10-K, which were prepared by or under the direction of (among others) Wadekar and Shah, . . . statements and omissions in the Company's Form 10-Q filings during the Class Period, all of which were prepared by or under the direction of (among others) Wadekar and Shah, . . . statements in the Company's press releases, which were prepared under the direction of, and approved by, Wadekar and Shah." (Am. Compl. ¶ 201.) Given these allegations and drawing all inferences in favor of Plaintiff, as this Court must when considering a motion to dismiss, this Court concludes that the Complaint sufficiently alleges that Shah participated, either directly or indirectly, in the preparation of at least some of the statements alleged to be false or misleading.

11, 12, 25, 71, 72, 74-77, 79-82, 84-87, 89-96, 99-111, 112-16, 118-21, 124, 126-27, 136.) While many of these documents contained correct information, Plaintiff alleges that the documents misrepresented the fact that Able was fully compliant with all FDA requirements and using cGMPs. (Am. Compl. ¶¶ 36, 75-77, 79-82, 85, 90, 93, 97, 99, 102-4, 107-8, 111, 115, 117, 119, 127.) When Able's non-compliance was disclosed on May 19, 2005, the market reacted quickly and adversely.

Alleging, as the Complaint does here, the significant decrease in stock price immediately following the disclosure of the adverse information satisfies the Third Circuit's standard for pleading materiality.

b. Scienter

Turning to the next factor – scienter – plaintiffs need to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). "A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely as* any other plausible opposing inference." Tellabs, 127 S.Ct. at 2513 (emphasis in original). A plaintiff may establish this strong inference of scienter "'either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" Suprema, 438 F.3d at 276 (quoting Burlington Coat, 114 F.3d at 1418 (citations omitted)). As the Third Circuit has observed, "[a] reckless statement is one '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 or is so obvious that the actor must have been aware of it.'"

In re Advanta Corp., 180 F.3d at 535 (quoting McLean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)).

The Third Circuit has stated that "[i]t is well established that a pleading of scienter 'may not rest on a bare inference that a defendant 'must have had' knowledge of the facts.'" In re Advanta Corp., 180 F.3d at 539 (quoting Greenstone v. Cambex Corp., 975 F.2d 22, 26 (1st Cir. 1992)). "Likewise, allegations that a securities-fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading are 'precisely the types of inferences which [courts], on numerous occasions, have determined to be inadequate to withstand Rule 9(b) scrutiny.'" Id. (quoting Maldonado v. Dominguez, 137 F.3d 1, 10 (1st Cir. 1998)). "Generalized imputations of knowledge do not suffice, regardless of the defendants' position within the company." Id.

Wadekar, Mauro, and Shah all argue that Plaintiff failed to allege scienter sufficiently. Specifically, they each argue that Plaintiff does not allege facts demonstrating that they either possessed motive and opportunity to commit fraud, or acted with recklessness, or consciously misbehaved. After reviewing the allegations in the Complaint, this Court concludes that Plaintiff has alleged scienter sufficiently by alleging that Wadekar, Mauro, and Shah were reckless in not knowing of the problems in Able's manufacturing process. That is, these individuals departed from the standards of ordinary care by, among other things, not adequately investigating or following up on the 2004 FDA Form 483 and warning letter.[20] Further, this Court concludes that

[20] During oral argument, counsel for Wadekar and Klemick argued that failing to follow up on the FDA warning letter did not rise to the level of recklessness. Rather, it constituted negligence, or mismanagement. (Tr. of Proceedings, June 11, 2007 79:13-79:22 (hereinafter "Tr.").) As discussed more fully below, this Court disagrees. Ignoring the FDA's admonishment was "an extreme departure from the standards of ordinary care."

this inference is far more plausible than any competing inference that could possibly be drawn from the facts alleged.

"In January 2004, the FDA initiated an inspection of [Able's] South Plainfield, New Jersey manufacturing facility. Following the inspection, the FDA issued to [Able] a Form 483 notice concerning [Able's] compliance with cGMP, including certain observations by the inspectors related to our failure to report adverse drug events in accordance with the applicable rules and regulations." (SEC Form 10-Q filed by Able Laboratories, Inc. on April 16, 2004 at 17, attached as Ex. S to the Decl. of Glenn S. Kerner, Esq. (hereinafter "Ex. S").)

On April 19, 2004, the FDA sent a further warning letter to Able regarding the problems identified during the inspection in January and February of 2004. (Am. Compl. ¶ 55.) Specifically, the FDA found that "(a) [t]he Company failed to report to the FDA regarding 27 adverse drug experience reports the Company received between January 2002 and January 2004; and (b) [t]he Company had not developed adequate written procedures for the surveillance, receipt, evaluation, and reporting of PADEs [Postmarketing Adverse Drug Experiences] to the

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Counsel for Wadekar and Klemick also argued that the violations noted in the warning letter – failure to report 27 adverse drug experiences ("ADEs") reports and failure to develop adequate written procedures for the reporting of postmarketing adverse drug experiences ("PADEs") to the FDA – were not sufficiently similar to the quality control problems that ultimately led to Able's downfall to serve as a basis for alerting the defendants to the underlying quality control problems. (Tr. 33:21-34:23, 37:11-38:5.) This Court recognizes that the reporting failures cited in the 2004 warning letter differ in specifics from the quality control problems that were uncovered in 2005. However, this Court believes that the precatory language in the FDA letter, namely that "[t]he specific violations noted in this letter are serious and may be symptomatic of serious underlying problems," was enough to put Defendants on notice that problems with functions other than the reporting of ADEs and PADEs could exist and should be investigated. Further, the violations noted in the warning letter, while differing in specifics from the later violations, were nonetheless violations of FDA requirements, just as the later violations were.

FDA." (Am. Comp. ¶ 54.) In addition, the warning letter stated that "[t]he specific violations noted in this letter are serious and may be symptomatic of serious underlying problems. You are responsible for investigating and determining the causes of the violations identified above and preventing recurrence of similar violations." (Am. Comp. ¶ 55.)

The Form 483 and the warning letter provided notice to the defendants that serious problems existed in the manufacturing process at Able, and even informed the defendants that they were responsible for following up on, and further investigating, the problems. Failing to investigate the FDA warning is an "extreme departure from the standards of ordinary care" and demonstrates that the defendants were reckless for not knowing their statements about Able's compliance with FDA standards and other quality control issues were false.

Plaintiff alleges additional facts that support an inference of recklessness. For example, the Complaint states that "[u]nder Shah's tutelage, bench chemists willfully misreported adverse quality control results and doctored lab notebooks. Shah himself openly flouted established rules, admitting to the FDA in 2004, as evidenced by the warning letter, that he never, during his tenure as the Quality Control director, reported Adverse Drug Events as the FDA policies required." (Am. Compl. ¶ 173.) Further, the Complaint alleges that Shah "ensur[ed] that the Company met regulatory reporting requirements and increased its revenues by falsifying quality control data and by issuing false regulatory reports to the FDA; [and] . . . orchestrat[ed] the misreporting of quality control data to the FDA by instructing bench chemists under his direct supervision to falsify the results of quality control tests." (Am. Compl. ¶ 212.)

The Third Circuit has observed that "courts have recognized that allegations of [Generally Accepted Auditing Standards] GAAS violations, coupled with allegations that significant 'red

flags' were ignored, can suffice to withstand a motion to dismiss." Suprema, 438 F.3d at 279. If alleged violations of accounting standards can form the basis of a finding of recklessness, this Court concludes that violating FDA rules, combined with actively encouraging the misreporting of test results, satisfies the recklessness standard.

Further, as head of Quality Control, Shah should have followed up on the issues identified in the FDA warning letter. These allegations assert sufficiently that Shah was reckless with respect to maintaining quality controls at Able, or with respect to not being aware of the existing problems, and this inference is more likely than any other inference that this Court can develop based on the allegations.[21]

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[21] Plaintiff asks this Court to take judicial notice of the underlying criminal charge in Shah's March 8, 2007 plea agreement (Crim. Action No. 07-198) – a one-count Information, charging Shah with conspiracy to commit securities fraud and distribute misbranded and adulterated drugs. Plaintiff also requests that, in reviewing Defendants' motions to dismiss, this Court take judicial notice of the guilty plea to the one count information entered into by Shashikant Shah, along with the related allocution, as well as the entry of judgment against him in a civil proceeding brought by the SEC. (Pls.' Req. for Judicial Notice of Recent Developments in Criminal and SEC Proceedings Against Def. Shashikant Shah, in Connection with the Pending Mot. to Dismiss 1.) Third Circuit precedent establishes that, in reviewing a motion to dismiss, a court may not consider matters outside the pleadings without converting the motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Prop., Inc., 184 F.3d 280, 287 (3d Cir. 1999). However, there are a few narrowly defined exceptions, which explicate types of material that may be considered without making such a conversion. Id.

The types of material that may be considered without converting a motion to dismiss into a motion for summary judgment are documents that are integral to the complaint and documents that are subject to judicial notice. Id.

A matter is integral to the complaint if it was explicitly relied on or mentioned in the complaint. Id. "[A] district court may examine an undisputedly authentic document . . . if the plaintiff's claims are based on the document." Id. (internal citations omitted). In the case at bar, Plaintiff has not relied on the guilty plea of defendant Shah. The guilty plea occurred after the Complaint was filed. Therefore, the guilty plea was not relied on nor was it integral to the Complaint.

As to Mauro, the Complaint alleges that "he presided over Able's regulatory compliance." (Am. Compl. ¶ 162.) The Complaint further alleges that "methods of altering test data were so blatant and systemic that it would have been impossible for senior managers reviewing [Quality Control] QC Laboratory notebooks, absent recklessness, to not detect the manipulation of results." (Am. Compl. ¶ 182.)[22] Having oversight responsibility for the quality control and regulatory compliance functions of Able, Mauro's receipt and review of the FDA

Furthermore, in reviewing a motion to dismiss, documents subject to judicial notice include matters of public record, orders, and items appearing in the record of the case. Buck v. Hampton Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006). Among the public records a court may examine in order to resolve a motion to dismiss is a judicial proceeding from a different court or case. S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir. 1999). During oral argument, Plaintiff's counsel referred this Court to the decision in Rothman v. Gregor, 220 F.3d 81, 92 (2d Cir. 2000) as support for Plaintiff's request that this Court take judicial notice of Shah's guilty plea allocution. In Rothman, the Second Circuit simply took notice of the filing of a complaint as a public record, and not of the facts alleged in the complaint. This is consistent with the Third Circuit's policy regarding judicial notice of other legal proceedings. Southern Cross, 181 F.3d at 427 n.7 ("Recently, courts and commentators have paid more attention to the distinction between judicially noticing the existence of prior proceedings and judicially noticing the truth of facts averred in those proceedings. It has been suggested that the appropriate analogy is the hearsay rule, which allows an out-of-court statement to be admitted into evidence for purposes other than establishing the truth of the statement.").

Taking judicial notice of the existence of other proceedings does not convert a motion to dismiss into a motion for summary judgment as long as the court does not take judicial notice of those proceedings to find facts. Id. at 426–27; see also Global Network Comm., Inc. v. City of New York, 458 F.3d 150, 157 (2d Cir. 2006) (stating that "[a] court may take judicial notice of a document filed in another court not for the truth of the matters asserted in the other litigation, but rather to establish the fact of such litigation and related filings"). Therefore, this Court may take judicial notice of the fact that Shah entered a guilty plea, but may not make findings of fact based on the proceedings or rely on the proceedings for the truth of the facts therein.

[22] As previously noted, the findings from the FDA Form 483, although issued in 2005 after the end of the Class Period, refer to events and conditions, including the falsification of data, that existed during the Class Period, and can be relied upon by Plaintiff in support of its allegations. In re Merck & Co., 432 F.3d at 271-72.

warning letter should have alerted him to potential problems within those areas. Ignoring the FDA warning letter, especially when "blatant and systemic" quality control violations were occurring in the lab, was an "extreme departure from the standards of ordinary care," and supports the conclusion that Mauro was reckless in not knowing of the compliance problems.[23] This conclusion is more likely than any other conclusion that this Court could draw from the facts alleged.

As to Wadekar, "[t]he FDA warning letter specifically noted that all of the deviations unearthed in the FDA's inspection had been presented to and discussed with Wadekar. . . . Yet, the FDA's warnings were ignored and Able's quality control and regulatory deficiencies were left unaddressed." (Am. Compl. ¶ 167.) The 2005 FDA investigation and Form 483 demonstrate that numerous problems with Able's quality controls continued after the April 19, 2004 warning letter put Wadekar, as well as the other defendants, on notice of the actual and potential violations. The Complaint also alleges that Wadekar hired inexperienced chemists. (Am. Compl. ¶ 169 ("as Wadekar, Shah, and the other Defendants knew from their observations of these chemists, these new hires lacked adequate training and frequently made errors").)

Additionally, beginning in January 2005, Able recalled several drugs due to a "failure to properly label the drugs in accordance with FDA regulations," (Am. Compl. ¶ 131), due to

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[23] During oral argument, counsel for Mauro argued that, based on the fact that as soon as Mauro learned of the quality control and compliance problems, he reported the problems to the FDA, he necessarily lacked scienter. (Tr. 67:7-67:14.) While this argument may be appropriate at a later stage of this case when evidence beyond the allegations of the complaint may be considered, it is not appropriate in evaluating the motions to dismiss. That is, in considering a motion to dismiss, this Court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party. Oshiver, 38 F.3d at 1384.

stability failures (Am. Compl. ¶ 132), and due to impurity failures (Am. Compl. ¶ 134). These recalls were not disclosed to investors. (Am. Compl. ¶¶ 131, 132, 136.) The fact that Wadekar knew of the FDA warning letter, and failed to take any action to address the continuing compliance problems, combined with the compliance problems disclosed by the recalls, allows this Court to infer Wadekar's recklessness.[24] This inference is more likely than any other inference that could be drawn from the facts alleged.

Since this Court concludes that the Complaint alleges scienter sufficiently by demonstrating the recklessness of Wadekar, Shah, and Mauro, and that the inference of recklessness is more likely than any other inference that could be drawn from the facts alleged, the motions to dismiss Count I of the Complaint will be denied.[25]

2. Rule 10b-5(a) and (c) Claims

Securities fraud cases brought under Section 10(b) and pursuant to Rule 10b-5(a) and (c)

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[24] During oral argument, counsel for Wadekar argued that Plaintiff failed to allege specific facts that demonstrated Wadekar's conscious wrongdoing. (Tr. 33:1-33:13.) While this may or may not be true, it is not relevant to the question of whether or not Plaintiff alleged sufficient facts to demonstrate Wadekar's recklessness. The Third Circuit requires plaintiffs to allege scienter by alleging motive and opportunity or by "'alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" Suprema, 438 F.3d at 276 (quoting Burlington Coat, 114 F.3d at 1418 (citations omitted) (emphasis added)). Since this Court concludes Plaintiff alleged facts demonstrating recklessness, Plaintiff need not also demonstrate conscious misbehavior since the standard proposes the two methods in the alternative, rather than the conjunctive.

[25] Since none of the defendants challenge the sufficiency of Plaintiff's pleading regarding any of the other factors required to demonstrate a violation of § 10(b), namely, connection with the purchase or sale of a security; reliance or, as it is sometimes referred to, "transaction causation;" economic loss; or loss causation, this Court need not address those factors.

differ from claims brought pursuant to Rule 10b-5(b) in one respect.[26] While Rule 10b-5(b) addresses liability for material misstatements or omissions, "Rules 10b-5(a) and (c) encompass conduct beyond disclosure violations." Benzon v. Morgan Stanley Distribs., Inc., 420 F.3d 598, 610 (6th Cir. 2005). Likewise, the Supreme Court observed that "the second paragraph of [Rule 10b-5] specifies the making of an untrue statement of material fact and the omission to state a material fact[; however,] [t]he first and third subparagraphs are not so restricted." Affiliated Ute Citizens v. United States, 406 U.S. 128, 152-53 (1972). In fact, the Supreme Court recently observed that the suggestion that "there must be a specific oral or written statement before there could be liability under § 10(b) or Rule 10b-5, . . . would be erroneous [since c]onduct itself can be deceptive." Stoneridge, 128 S. Ct. at 769.

Subsections (a) and (c) of Rule 10b-5, specifically, impose liability for the use of "any device, scheme, or artifice to defraud" or for "engag[ing] in any act, practice, or course of business which operates . . . as a fraud." 17 C.F.R. § 240.10b-5(a), (c). Other district courts have concluded that, in order to state a claim under subsections (a) or (c), "'a plaintiff must allege that

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[26] Rule 10b-5 deems it unlawful:

> (a) [t]o employ any device, scheme, or artifice to defraud,
>
> (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.

17 C.F.R. § 240.l0b-5.

defendant (1) committed a manipulative or deceptive act (2) in furtherance of the alleged scheme to defraud, (3) scienter, and (4) reliance.'"[27] In re Royal Dutch/Shell Transp. Sec. Litig., No. 04-CV-347 (JAP), 2006 U.S. Dist. WL 2355402, at *7 (D.N.J. Aug. 14, 2006) (quoting In re Global Crossing, 322 F. Supp. 2d at 336).

This Court finds that these district courts failed to consider the Supreme Court's pronouncement in Dura with respect to the pleading requirements for claims brought under § 10(b) when they concluded that only those four elements were necessary to state a claim under Rule 10b-5(a) and (c).[28] In Dura, the Supreme Court clarified that in order to state a claim under § 10(b) a plaintiff must plead loss causation, reliance, and economic loss,[29] in addition to pleading scienter, a connection with the purchase or sale of a security, and a material

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[27] Given the specific language of Rule 10b-5, it appears to this Court that an individual deceptive act could be enough by itself, without being part of a scheme, to state a claim under Rule 10b-5(a) or (c). That is, the only mention of scheme in Rule 10b-5 is in subsection (a), which prohibits the use of "any device, scheme or artifice to defraud." 17 C.F.R. § 240.10b-5(a). The use of "or" in this subsection indicates that engaging in any one of the three forms of conduct by itself would constitute a violation of the rule. It is not necessary for the action to be taken as part of a scheme. This conclusion is supported by the Supreme Court's conclusion in Stoneridge that "[c]onduct itself can be deceptive." Stoneridge, 128 S. Ct. at 769. Further, in discussing the connection between reliance and causation as elements of a claim under § 10(b), the Supreme Court discussed deceptive acts, and made no mention of there being any requirement that the acts be part of a larger scheme. Id. In fact, the dissent agreed that "[t]he Court correctly explains why the statute covers nonverbal as well as verbal deceptive conduct." Id. at 775 (Stevens, J., dissenting).

[28] The decisions in Global Crossing were issued before the Supreme Court decided Dura, while the decision in Royal Dutch Shell was issued after Dura.

[29] In reaching this conclusion, the Supreme Court applied the provisions of 15 U.S.C. § 78u-4(b)(4), which provides that "[i]n any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." Dura, 544 U.S. at 343 ("To 'touch upon' a loss is not to *cause* a loss, and it is the latter that the law requires." (emphasis in original) (citing 15 U.S.C. § 78u-4(b)(4))).

misrepresentation or omission. Dura, 544 U.S. at 341-42. In fact, the Court noted that "[t]he statute thereby makes clear Congress' [sic] intent to permit private securities fraud actions for recovery where, but only where, plaintiffs adequately allege and prove the traditional elements of causation and loss." Id. at 346.

In setting out these elements, the Supreme Court noted that "Rule 10b-5 forbids, among other things, the making of any 'untrue statement of a material fact' or the omission of any material fact 'necessary in order to make the statements made . . . not misleading.'" Id. at 341 (quoting 17 C.F.R. § 240.10b-5).[30] The Supreme Court did not limit its interpretation of the statute to only those securities fraud claims based on misstatements or omissions; rather, the Supreme Court simply observed that misstatements or omissions were some of, but not the only, prohibited conduct described in Rule 10b-5.

In Stoneridge, the Supreme Court emphasized that "Rule 10b-5 encompasses only conduct already prohibited by § 10(b)." Stoneridge, 128 S. Ct. at 768. Therefore, this Court concludes that, in order to state a claim under Rule 10b-5(a) and (c), a plaintiff must allege that the defendant employed a device, scheme or artifice to defraud, or engaged in an act, practice or course of business which would operate as a fraud, in addition to the final five elements set forth

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[30] Since a claim under 10b-5(b) involves making false or misleading statements or omissions of material fact, the pleading requirements of 15 U.S.C. § 78u-4(b)(1) apply. However, the pleading requirements of 15 U.S.C. § 78u-4(b)(1) do not apply to Rule 10b-5(a) and (c) claims, since claims under (a) and (c) involve actions instead of statements. See In re Royal Dutch/Shell, 2006 U.S. Dist. WL 2355402 at *7 ("While the pleading requirements of 15 U.S.C. § 78u-4(b)(2) and Rule(9) apply to Rule 10b-5(a) and (c) claims, the pleading requirements of 15 U.S.C. § 78u-4(b)(1) do not."); Global Crossing, 322 F. Supp. 2d at 330 n.7 ("[t]he requirement of 15 U.S.C.A. § 78u-4(b)(1) obviously does not apply to claims brought under Rule 10b-5(a) or (c), as such claims do not rely on allegations of material misstatements or omissions").

in Dura, namely "[(1)] scienter, i.e., a wrongful state of mind; [(2)] a connection with the purchase or sale of a security; [(3)] reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation'; [(4)] economic loss; and [(5)] 'loss causation,' i.e., a causal connection between the material misrepresentation and the loss." Dura, 544 U.S. at 341 (internal citations omitted).

In addition, FED. R. CIV. P 9(b) requires particularized pleading of "'what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities at issue.'" In re Royal Dutch/Shell, 2006 U.S. Dist. WL 2355402 at *7 (quoting In re Parmalat Sec. Litig., 414 F. Supp. 2d 428, 432 (SDNY 2006)). See also In re Global Grossing, 322 F. Supp. 2d at 329.

Claims made under all sections of Rule 10b-5 include a showing of scienter and are thus held to the heightened pleading requirements of FED. R. CIV. P. 9(b) and 15 U.S.C. § 78u-4(b)(2).[31] That is, a claim made pursuant to Rule 10b-5(a) and (c) rests on a claim that a defendant had the requisite state of mind to either employ a device, scheme or artifice to defraud or participate in an act or practice to defraud investors. 17 C.F.R. §§ 240.10b-5(a), (c). As fraud is the underlying theory of 10b-5(a) and (c) claims, and scienter is a traditional element of a fraud claim, the heightened pleading standards apply.

The Supreme Court has noted that the legislative history of section 10(b) also supports a conclusion that scienter is a necessary element for all securities fraud actions brought under

[31] Pursuant to 15 U.S.C. § 78u-4(b)(2), "[i]n any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."

section 10(b), including actions brought pursuant to Rule 10b-5(a) and (c). Ernst & Ernst, 425 U.S. at 201-02 (1976) ("[W]e think the relevant portions of that [legislative] history support our conclusion that § 10(b) was addressed to practices that involve some element of scienter . . . and [t]here is no indication . . . that § 10(b) was intended to proscribe conduct not involving scienter.").

Accordingly, pursuant to 15 U.S.C. § 78u-4(b)(2), a plaintiff bringing an action under Rule 10b-5(a) and (c) must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."

a. Analysis

In the instant action, Count II of the Complaint alleges that, in addition to the misstatement and omissions of material fact, Wadekar and Shah used devices, schemes, or artifices or engaged in conduct to defraud investors, in violation of Rule 10b-5(a) and (c).[32] (Am. Compl. ¶ 212.)

Commission of a manipulative or deceptive act in furtherance of a scheme to defraud is the initial step in the analysis of a Rule 10b-5(a) and (c) claim. In re Royal Dutch/Shell, 2006 U.S. Dist. WL 2355402 at *7. While, as this Court has already stated, it is not necessary for a plaintiff to allege acts in furtherance of a scheme to defraud, this Court agrees that the first step in analyzing a claim made pursuant to Rule 10b-5(a) and (c) is the determination of whether the

[32] As this Court observed in In re Genta, Inc., "the reach of Rule 10b-5(c) is very broad: that provision makes it unlawful to 'engage in any act . . . which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.' If the Complaint supports a claim for making an untrue statement, and also supports an inference of scienter for fraud, under Rule 10b-5(b), it must logically support a claim for an act to defraud under Rule 10b-5(c): making an untrue statement with scienter for fraud is an act to defraud." In re Genta, Inc., No. 04-CV-2123, slip op. at 12-13 (D.N.J. Sept. 29, 2005) (JAG).

plaintiff has alleged that defendant has "employ[ed] any device, scheme or artifice to defraud" or "engage[d] in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. §§ 240.10b-5(a), (c).

As noted above, a plaintiff will satisfy the heightened pleading requirements if the complaint alleges, "with particularity, what manipulative acts were performed, which defendants performed them, [and] when the manipulative acts were performed." In re Royal Dutch/Shell, 2006 U.S. Dist. WL 2355402 at *7.

To that end, Plaintiff contends that Shah and Wadekar, "individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of a national securities exchange: a. employed devices, schemes, and artifices to defraud; and b. engaged in acts, practices, and a course of conduct that operated as a fraud or deceit upon Plaintiffs and other members of the Class." (Am. Compl. ¶ 211.) The specific fraudulent devices, schemes, artifices, and other conduct that Plaintiff attributes to Shah include "(a) . . . ensuring that the company met regulatory reporting requirements and increased its revenues by falsifying quality control data and by issuing false regulatory reports to the FDA; (b) . . . orchestrating the misreporting of quality control data to the FDA by instructing bench chemists under his direct supervision to falsify the results of quality control tests; [and] (c) . . . failing to report adverse drug events to the FDA throughout his tenure at the Company." (Am. Compl. ¶ 212.) Plaintiff cites Wadekar's alleged "complicity with Shah to conceal adverse quality control results from the FDA even after the FDA warned of grave problems in Able's quality controls," as conduct that constitutes a manipulative act or deceptive conduct. (Am. Compl. ¶ 212(e).) As for conduct attributable to both Wadekar and Shah, Plaintiff alleges that

they "hir[ed] inexperienced and poorly trained bench chemists and foster[ed] a culture of dishonesty to conceal adverse quality control results." (Am. Compl. ¶ 212(d).)

Based on these allegations of specific acts committed by Wadekar and Shah, this Court concludes that Plaintiff has satisfied the first prong of the pleading requirement of a Rule 10b-5(a) and (c) claim.

Wadekar does not distinguish his opposition to Plaintiff's 10b-5(b) claim and 10b-5(a) and (c) claim; he simply argues that the Complaint fails to allege scienter sufficiently. As previously discussed, this Court concludes that the Complaint alleges scienter adequately by alleging specific facts demonstrating Wadekar's recklessness, and that this inference is more likely than any other inference that could be drawn from the alleged facts. Therefore, Wadekar's motion to dismiss this count of the Complaint will be denied.

As he did in opposition to Count I, Shah argues that Plaintiff fails to allege scienter sufficiently. As with Wadekar, this Court has already concluded that the Complaint adequately alleges scienter based on assertions of recklessness.

Additionally, in moving to dismiss Count II, Shah argues that Plaintiff attempts to allege his participation in a scheme to defraud based on aiding and abetting liability. Specifically, Shah argues that Count II of the Complaint must be dismissed because Plaintiff merely alleged that Shah participated in a scheme to defraud investors, but failed to allege that Shah was an "architect" or "mastermind" of the scheme to defraud. (Shah Mem. to Dismiss 15-16.) While Shah is correct that, pursuant to Rule 10b-5(a) and (c), Plaintiff must do more than allege that a defendant participated in manipulative conduct or a deceptive scheme that involved misrepresentations to investors, In re Royal Dutch/Shell, 2006 U.S. Dist. WL 2355402 at *8, he

misstates what that something more is. Rather than allege that Shah was the architect of the scheme, Plaintiff must allege that Shah participated in a manipulative scheme or deceptive conduct that goes beyond misrepresentations. Id.

To be sure, the Supreme Court observed in Central Bank of Denver, N.A. v. First Interstate Bank of Denver that a plaintiff may not bring a private action under § 10(b) and pursuant to Rule 10b-5 for conduct that amounts to aiding and abetting. 511 U.S. at 191 (holding "that a private plaintiff may not maintain an aiding and abetting suit under § 10(b)").

However, while the Central Bank holding prohibits extending § 10(b) liability to aiders and abetters, it does not limit liability solely to architects or masterminds of a scheme to defraud. Id. (noting that "the absence of § 10(b) aiding and abetting liability does not mean that secondary actors in the securities markets are always free from liability under the securities Acts."). Instead, the Supreme Court held that "[a]ny person or entity, including a lawyer, accountant, or bank, who employs a manipulative device . . . on which a purchaser or seller of securities relies may be liable as a primary violator under 10b-5, assuming *all* of the requirements for primary liability under Rule 10b-5 are met." Id. The Supreme Court recently reaffirmed this holding in Stoneridge. Stoneridge, 128 S. Ct. at 769 ("The conduct of a secondary actor must satisfy each of the elements or preconditions for liability."). Therefore, Plaintiff is not required to allege that Shah was an architect or mastermind of the scheme to defraud investors.

Plaintiff adequately alleges specific instances of manipulative and deceptive conduct on the part of Shah and Wadekar. Plaintiff's Complaint highlights three years of conduct – during the relevant class period – in which all of the defendants, including Shah and Wadekar, "falsif[ied] test results, tamper[ed] with computer data, forge[d] records . . . [and] fabricated in

house test data to meet FDA standards." (Am. Compl. ¶ 51.) This deceptive conduct effectuated the continued manufacturing and distribution of Able's products, while concealing its noncompliance with FDA regulations.

After drawing all inferences in favor of Plaintiff, as is required on a motion to dismiss, this Court finds that Plaintiff has pled with specificity conduct and participation in a deceptive scheme that involves misrepresentation. Plaintiff has not attempted to circumvent Central Bank's prohibition against extending a private cause of action to aiders and abetters.[33] Rather, the Complaint includes particularized allegations that Shah and Wadekar engaged in manipulative conduct in furtherance of a scheme to defraud in violation of Rule 10b-5(a) and (c).

The motions to dismiss Count II of the Complaint will be denied.

D. Section 18 of the Securities Exchange Act of 1934

Before reaching the merits of the Section 18 claim, this Court must address the question of whether or not the Section 18 claim is time-barred.

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[33] During oral argument, counsel for Shah drew this Court's attention to decisions from several courts of appeals, see, e.g., Regents of the Univ. of Cal. v. Credit Suisse First Boston (USA), Inc., 482 F.3d 372 (5th Cir. 2007); Simpson v. AOL Time Warner Inc., 452 F.3d 1040 (9th Cir. 2006), and a recently granted petition of certiorari, Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 127 S. Ct. 1873 (2007), in an effort to demonstrate that the definition of scheme liability is in flux. (Tr. 56:15-57:21.) The Supreme Court's recent decision in Stoneridge does not focus on the definition of scheme liability, but rather involves the question of liability of outside third parties – suppliers and customers – who participated in a scheme to defraud investors. Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 128 S. Ct. 761 (2008). In fact, the Supreme Court concluded that, while secondary actors could not be found liable under an aiding and abetting theory, "the implied right of action in § 10(b) continues to cover secondary actors who commit primary violations." Id. at 773-74. In stark contrast, the allegations before this Court involve high ranking officers of the Company, and not outside third parties. As a result, the cases cited by Shah's counsel are not applicable to this Court's evaluation of the present case.

1. Timeliness of Section 18 Claim

Section 18 of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78r, provides an express statute of limitations for any claims that allege a violation of that section. According to § 18(c), "[n]o action shall be maintained to enforce any liability created under this section unless brought within one year after the discovery of the facts constituting the cause of action and within three years after such cause of action accrued." 15 U.S.C. § 78r(c). Plaintiff acknowledges that this claim is untimely based on the one-year statute of limitations period expressed in § 18 of the Exchange Act because "the truth [about the FDA violations] was publicly disclosed . . . in late May 2005 " (Opp'n to Def.'s Mot. to Dismiss 61.), and this claim was first asserted in the amended complaint filed in June 2006 (Am. Compl. ¶¶ 137-41).

However, Plaintiff asserts that the § 18 claim is governed by the extended two-year statute of limitations period expressed in § 804 of the Sarbanes-Oxley Act ("SOX"), which provides that

> a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws . . . may be brought not later than the earlier of 2 years after the discovery of the facts constituting the violation; or 5 years after such violation.

28 U.S.C. § 1658(b). As such, Plaintiff argues that this claim is not time-barred because it was filed within two years from the discovery of the facts constituting the violation. (Opp'n to Def.'s Mot. to Dismiss 65.) However, federal courts have not reached uniformity on the issue of whether the statute of limitations expressed in § 804 of SOX overrides the statute of limitations expressed in § 18 of the Exchange Act. Compare In re Alstom SA Sec. Litig., 406 F. Supp. 2d 402, 420 (S.D.N.Y. 2005) (hereinafter "Alstom") (holding SOX statute of limitations

inapplicable to claim under § 18 of the Securities Exchange Act) with Teachers' Ret. Sys. of La. v. Qwest Commc'ns Int'l, Inc., Civ. No. 04-0782, 2005 U.S. Dist. WL 2359311 at *3 (D. Colo. 2005) (holding SOX statute of limitations applicable to claim under Section 18 of the Securities Exchange Act).

The Third Circuit has not decided the issue,[34] and the only court within the circuit to consider it held that the SOX statute of limitations did not apply to claims brought under § 18 of the Exchange Act. See WM High Yield Fund v. O'Hanlon, No. 04-3423, 2005 U.S. Dist. LEXIS 12064, *38 (E.D. Pa. May 13, 2005).

This Court is persuaded by courts holding that the SOX statute of limitations is inapplicable to claims under § 18 of the Exchange Act. When construing a statute, the Court

> begins with the language of the statute. The first step "is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." The inquiry ceases "if the statutory language is unambiguous and' the statutory scheme is coherent and consistent.'"

Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002) (quoting Robinson v. Shell Oil Co., 519 U.S. 337, 340 (2002) (internal citations omitted)). Here, the plain language of § 804 of SOX indicates that it only applies to causes of action involving claims of fraud. Several courts have concluded that claims of fraud under the securities laws require plaintiffs to plead fraudulent intent. See Ross v. A.H. Robins Co., 607 F.2d 545, 555–56 (2d Cir. 1979); O'Hanlon, 2005 U.S.

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[34] In an unpublished non-precedential opinion, the Third Circuit found that a complaint, alleging a violation of § 13(d)(3) of the Securities Exchange Act of 1934, was time-barred under both the Act's explicit one-year limitations period and the SOX's two-year limitations period. Ronson Co. v. Steel Partners II. L.P., 119 F. App'x 392, 394 (3d Cir. 2005). This claim did not involve a violation of § 18 of the Exchange Act and it was unnecessary for the court to determine whether the SOX statute of limitations overrode the express limitations period in § 13 of the Exchange Act because the plaintiff's claim was time-barred under both limitations periods. Id.

Dist. LEXIS 12064 at *38; In re Global Crossing, 313 F. Supp. 2d 189, 197 (S.D.N.Y. 2003). Furthermore, the Third Circuit has stated that neither scienter nor any particular state of mind is an element of a claim under § 18 of the Exchange Act. Suprema, 438 F.3d at 283. Therefore, the statute of limitations expressed in § 804 of SOX should not apply to claims under § 18 of the Exchange Act.[35]

Additionally, § 18, unlike other sections of the Exchange Act – such as § 10(b) – has an express limitations provision. 15 U.S.C. § 78r(c). As noted by other courts, there is no indication in SOX of a clear intent to overrule express limitations periods in the Exchange Act. See, e.g., Alstom, 406 F. Supp. 2d at 420. Therefore, it is logical to conclude that the limitations period expressed in § 804 of SOX was only intended to apply to implied causes of action with no express limitations period. Id.

Discussing the difference between implied and express causes of action under the Exchange Act, Justice Kennedy, dissenting in Lampf v. Gilbertson, stated that the

> purpose and underlying rationale [of Sections 18 and 9 of the Exchange Act] differ from causes of action implied under § 10(b). . . . Neither relates to a cause of action of the scope and coverage of an implied action under § 10(b). Nor does either rest on the common-law fraud model underlying most § 10(b) actions.

Lampf v. Gilbertson, 501 U.S. 350, 375–76 (1991) (Kennedy, J., dissenting). This reasoning supports the notion that the SOX statute of limitations was intended to treat claims under § 18 of the Exchange Act differently from claims under § 10(b) of the Exchange Act, by interfering with the latter, but not the former.

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[35] Applying similar reasoning, the Third Circuit concluded that the statute of limitations in SOX did not apply to claims brought under § 14(a) of the Securities Exchange Act since "[v]iolations of § 14(a) . . . may be committed without scienter; in other words, no culpable intent is required." In re Exxon Mobil Corp. Sec. Litig., 500 F.3d 189, 196 (3d Cir. 2007).

Plaintiff alternatively contends that the claim under § 18 of the Exchange Act is not time-barred because it relates back to the original complaints, pursuant to FED. R. CIV. P. 15(c). Wadekar, who was named in each of the original complaints in this case, is the only defendant that Plaintiff names in the amended complaint for violating § 18 of the Exchange Act. (Am. Compl. Count IV.)

According to FED. R. CIV. P. 15(c)(1)(B), a claim relates back to the original complaint if it arises "out of the conduct, transaction, or occurrence set out – or attempted to be set out – in the original pleading." Plaintiff's allegations of the statements on the forms filed with the SEC and the certification of those forms by Wadekar provides much of the basis for the § 10(b) claims found in the original complaints. (See nine original complaints in Civil Action Nos. 05-2681, 05-2683, 05-2684, 05-2685, 05-2810, 05-3013, 05-3068, 05-3083, 05-3378.) Claims for violations of both § 10(b) and § 18 of the Exchange Act require a plaintiff to plead material misstatements or omissions that caused injury in connection with the purchase or sale of securities, and in fact the same material misstatement or omission can be the basis for both claims. See Suprema, 438 F.3d at 283. Moreover, the only difference between pleading claims under § 18 of the Exchange Act and § 10(b) of the Exchange Act is that § 18 requires that a plaintiff sufficiently pleads reliance but not scienter, while § 10(b) requires that a plaintiff sufficiently pleads scienter but not reliance. See Suprema, 438 F.3d at 283.

Here, Plaintiff's allegations of the conduct providing the basis for the § 10(b) claims in the original complaints is the same conduct that provides the basis for the § 18 claim in the amended complaint. (Am. Compl. Count IV.) The similarity between pleading these two causes of action significantly attenuates any argument that the § 10(b) claims in the original complaints

were insufficient to provide notice of a potential § 18 claim.

This Court finds that the § 18 claim against Wadekar is not time-barred because it relates back to the original complaints under FED. R. CIV. P. 15(c). Wadekar is a party in each of the original complaints and the § 18 claim in the amended complaint is based on the same conduct and occurrences as the § 10(b) claims in the original complaints.

2. Section 18 Claim Analysis

Section 18 of the Exchange Act creates a private remedy for damages resulting from the purchase or sale of a security in reliance upon a false or misleading statement contained in any document or report filed with the SEC pursuant to the Exchange Act, unless the defendant can prove that he or she acted in good faith and without knowledge of the statement's falsity. Suprema, 483 F.3d at 283. Section 18(a) of the Exchange Act, 15 U.S.C. § 78r(a), provides in part that

> Any person who shall make or cause to be made any statement in any application, report, or document filed pursuant to this chapter or any rule or regulation thereunder or any undertaking contained in a registration statement as provided in subsection (d) of section 78o of this title, which statement was at the time and in the light of the circumstances under which it was made false or misleading with respect to any material fact, shall be liable to any person (not knowing that such statement was false or misleading) who, in reliance upon such statement, shall have purchased or sold a security at a price which was affected by such statement, for damages caused by such reliance, unless the person sued shall prove that he acted in good faith and had no knowledge that such statement was false or misleading.

15 U.S.C. § 78r(a).

Section 18 only pertains to false or misleading statements that appear in reports or documents filed pursuant to the Securities Exchange Act of 1934. 15 U.S.C. § 78r(a) (specifying that liability extends for reports or documents that were "filed pursuant to this chapter or any rule

or regulation thereunder"); Suprema, 438 F.3d at 283. Therefore, § 18 does not apply to documents filed pursuant to other securities laws, such as the Securities Act of 1933. Alstom, 406 F. Supp. 2d at 479. Additionally, the SEC regulations specifically exempt certain filings from the provisions of § 18 — such as Form 6-K and part I of Form 10-Q — while expressly determining that other forms do fall within the ambit of § 18 — such as Form 10-K and Form 10-KSB. See, e.g., 17 C.F.R. § 240.13a-16(l) (exempting Form 6-K); 17 C.F.R. § 240.15d-16(l) (exempting Form 6-K); 17 C.F.R. § 240.13a-13(d) (exempting information on Part I of Form 10-Q); 17 C.F.R. § 240.14a-3(d) (including Form 10-K); see also Alstom, 406 F. Supp. 2d at 479.

Section 18 claims differ from claims based on section 10(b) of the Exchange Act primarily in terms of reliance and scienter. Suprema, 438 F.3d at 283 ("[U]nlike a Section 10(b) claim, liability under Section 18 requires proof of reliance but does not require proof of scienter."). "A section 18 plaintiff . . . bears no burden of proving that the defendant acted with scienter or any particular state of mind." Id. Instead, the burden of proving state of mind falls upon the defendant, who must demonstrate good faith and lack of knowledge that the statement on the filing was false or misleading. Ross, 607 F.2d at 555–56; Brody v. Stone & Webster, Inc., 414 F.3d 187, 193 (1st Cir. 2005); Alstom, 406 F. Supp. 2d at 480. This burden on the defendant is in the form of an affirmative defense. Alstom, 406 F. Supp. 2d at 480. Therefore, a strong inference of scienter, required pursuant to the PSLRA in order to bring a claim under § 10(b) of the Exchange Act, is unnecessary for claims under § 18. Id. This does not eliminate the other heightened pleading requirements imposed by the PSLRA. See Alstom, 406 F. Supp. 2d at 482-83.

However, a § 18 plaintiff does need to allege actual reliance on specific statements in the

SEC filing at issue; a presumption of reliance will not suffice. Suprema, 438 F.3d at 283; Ross, 607 F.2d at 552–53; In re Alstom, 406 F. Supp. 2d at 479. For a § 18 claim, "merely alleg[ing] . . . reli[ance] on the documents that contained misstatements" is not enough without allegations of "actual reliance on the *specific misrepresentations* themselves." Suprema, 438 F.3d at 283 (emphasis added). In addition, the plaintiff must allege a causal nexus between the sale of a security and actual reliance upon the false or misleading statement or omission. Id. at 284.

The Third Circuit has not determined whether the heightened pleading requirements of Rule 9(b) apply to § 18 claims. Suprema, 438 F.3d at 283 n.13. Some other courts require that complaints under § 18 meet the heightened pleading requirements of FED. R. CIV. P. 9(b), if the pleading sounds in fraud. See, e.g., Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978); Rombach v. Chang, 355 F.3d 164, 171 (2d Cir. 2004); In re Alstom, 406 F. Supp. 2d at 483. "[A] complaint can sound in fraud under Rule 9(b) even if fraud is not an element of the cause of action." In re Alstom, 406 F. Supp. 2d at 483 n.45 (citing Rombach, 355 F.3d at 171). "A claim sounds in fraud if its words and imputations include characterizing a document as 'inaccurate and misleading' or containing 'untrue statements of material facts,'" or other words and imputations that are traditionally characterized as fraud. In re Alstom, 406 F. Supp. 2d at 483 n.45 (quoting Rombach, 355 F.3d at 172).

In the instant case, Plaintiff alleges a violation of § 18 of the Securities Exchange Act only against Wadekar. (Am. Compl. ¶ 232.) Plaintiff specifically alleges that Wadekar was

responsible[36] for false statements contained in the 2003 Form 10-K, which was filed with the SEC. (Am. Compl. ¶ 233.) Further, Plaintiff alleges that the misleading statements in the 2003 Form 10-K were that Able "'believe[s] that [it is] currently in compliance with all applicable FDA requirements' and '[Able] do[es] not expect the law [providing for penalties for wrongdoing in connection with the development or submission of an ANDA] to have a material impact on the review or approval of [its] ANDAs.'" (Am. Compl. ¶ 235(a) (quoting 2003 Form 10-K).) Plaintiff also points to the company's assertion that certain ANDAs had been approved by the FDA in accordance with sound cGMPs.[37] (Am. Compl. ¶ 235(b) (quoting 2003 Form 10-K).)

Plaintiff alleges specific statements made on a specific form that was filed with the SEC. Furthermore, Plaintiff pleads that the statements were read and relied upon in connection with the purchase of Able securities (Am. Compl. ¶ 238), thus satisfying the actual reliance requirement. Suprema, 438 F.3d at 283. Therefore, even applying the heightened pleading standard of FED. R. CIV. P. 9(b) to this claim under § 18, Plaintiff has pled adequately a violation

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[36] Plaintiff specifically identifies Wadekar's certification on the 2003 Form 10-K, which states that

> [b]ased on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report.

(Am. Compl. ¶ 235(c).)

[37] The ANDAs were for Acetaminophen and Codeine Phosphate Tablets, USP 300mg/30mg; Diphenoxylate and Atropine Sulfate Tablets; Methylphenidate Hydrochloride Tablets; Methylphenidate Hydrochloride Extended Release Tablets; Nitroglycerine Sublingual Tablets; Prochloroperazine Suppositories; and Proproxyphene Napsylate and Acetaminophen Tablets. (Am. Compl. ¶ 235(b).)

by identifying specific statements and pleading actual reliance on those statements.

Accordingly, the motion to dismiss Count IV of Plaintiff's Amended Complaint — violation of § 18 of the Securities Exchange Act against Wadekar — will be denied.

E. Insider trading

Section 20A of the Securities Exchange Act of 1934, 15 U.S.C. § 78t-1, establishes a private right of action for insider trading. Specifically, that section provides

> Any person who violates any provision of this chapter or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable in an action in any court of competent jurisdiction to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities) securities of the same class.

15 U.S.C. § 78t-1(a).

Thus, in order to plead a violation of this provision, plaintiffs must first plead a predicate violation of the Securities Exchange Act of 1934, as well as pleading that the purchase or sale of the securities occurred contemporaneously with the insider's sale or purchase of the same securities. As discussed earlier, this Court has concluded that Plaintiff satisfied the pleading requirements established by § 10(b).[38] Therefore, this Court will turn to the second requirement:

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[38] Wadekar argues that Plaintiff fails to allege that he was aware of materially adverse non-public information on October 2, 2003 – the date of his contemporaneous trade. (Mem. of Law of Defs. Dhananjay G. Wadekar and Iva Klemick in Support of their Mot. to Dismiss Consol. Class Action Compl. (hereinafter "Wadekar Mem. of Law") 30.) However, the Complaint alleges that, as far back as 2001, compliance issues existed at Able. For example, CW3 stated that during her time at Able as Quality Assurance inspector, many reports of quality assurance problems that were uncovered during inspections were left unaddressed by Quality Assurance managers. (Am. Compl. ¶ 165.) In particular, CW3 indicated that "when she reported variances in the thickness of pills that she was in charge of inspecting, she was told to change the reported results to reflect an in-range measurement. [Also,] when Able's label generating machines produced inaccurate label production numbers – which were reportable incidents – she

contemporaneous trading.

Section 20A does not define "contemporaneous." Rather, Congress seems to have chosen to leave to the courts defining the term "contemporaneous" on a case-by-case basis. H.R. Rep. No. 100-910, at 27 (1988), reprinted in 1988 U.S.C.C.A.N. 6043, 6064 ("The bill does not define the term 'contemporaneous,' which has developed through case law."). However, it appears that the Third Circuit has not defined "contemporaneous" for purposes of Section 20A. Various district courts have seemed to define "contemporaneous" rather narrowly – that is, requiring trading to occur within a day.[39]

The rationale behind this theory was explained clearly by Judge Smith (N.D. Cal.) in an unpublished opinion:

> The requirement of contemporaneousness developed as a proxy for the traditional requirement of contractual privity between plaintiffs and defendants. Since identifying the party in actual privity with the insider is virtually impossible in transactions occurring on an anonymous public market, the contemporaneousness standard was developed to give plaintiffs a more feasible avenue by which to sue insiders. William Wang, The Contemporaneous Traders

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was told by managers to alter her report to reflect the normal label quantity count." (Id.) Therefore, the Complaint adequately alleges that the pervasive problems at Able forming the basis of this Court's inference that Wadekar was reckless in not knowing of the compliance problems existed at the time of Wadekar's trade on October 2, 2003.

[39] See, e.g., In re MicroStrategy, Inc. Sec. Litig., 115 F. Supp. 2d 620, 662-63 (E.D. Va. 2000) ("Nor are decisions from other circuits uniform; courts elsewhere have applied varying definitions of contemporaneity . . . . Yet, as recognized by one district court, 'the growing trend among district courts in a number of circuits . . . is to adopt a restrictive reading of the term 'contemporaneous' at least with respect to shares heavily traded on a national exchange.'") (quoting In re AST Research Sec. Litig., 887 F. Supp. 231, 233 (C.D. Cal. 1995) (footnotes omitted)); Copland v. Grumet, 88 F. Supp. 2d 326, 338 (D.N.J. 1999) ("in order to satisfy the 'contemporaneous' requirement applied in insider trading claims under §§ 10(b) and 20A of the Exchange Act, a plaintiff must at this stage plead that he or she bought stock on the same dates on which the defendant's sales took place"); In re AST Research, 887 F. Supp. at 234 ("The same day standard is the only reasonable standard given the way the stock market functions.").

> Who Can Sue an Inside Trader, 38 Hastings L. Rev. 1175 (1987). The requirement was intended to preserve the notion that only plaintiffs who were harmed by the insider could bring suit, while nonetheless making it possible for such persons to bring suit. While an actual trade between plaintiff and defendant need not be expressly shown, harm to the plaintiff is a necessary factor. Such harm may be found where it appears the plaintiff might, in fact, have traded with the defendant.
>
> In this case, it is manifest that plaintiff could not have traded with defendant. Assuming that plaintiff bought CF shares on February 10, 1989, his purchase was still a minimum of three business days after defendant's sale. Given that 140,000 shares of CF stock were traded on Tuesday, February 7, the date of defendant's last sale, it seems apparent that plaintiff, trading three days later, could not have bought defendant's shares. Furthermore, plaintiff paid $35.249 for each of his shares. On the three days that defendant traded, by contrast, his shares were sold for $36.75 per share. Thus, the purchasers of defendant's shares paid $1.50 more than did plaintiff. Under these circumstances, where it is clear that plaintiff could not have traded with defendant, there is no reason for the Court to apply a more liberal standard to determine contemporaneousness.

Buban v. O'Brien, No. 94-0331, 1994 WL 324093, at *3 (N.D. Cal. June 22, 1994) (footnote omitted).

This Court agrees with the reasoning of Judge Smith and the other district courts noted above regarding the need for a narrow definition of "contemporaneous," at least in a case, such as this, involving a publicly traded company with millions of outstanding shares. Therefore, in order to satisfy the contemporaneity prong of section 20A, Plaintiff must allege that the insider trading occurred on the same day as Plaintiff's trade.

Since Plaintiff's allegations are based on Wadekar's and Shah's sale of stock, Plaintiff must allege that it bought stock contemporaneously with their sale. Plaintiff alleges that, on October 2, 2003, Wadekar sold 10,000 shares[40] and Shah sold 6,000 shares (Am. Compl. ¶ 185),

[40] Wadekar argues that, since this stock sale "occurred pursuant to a pre-existing trading plan adopted under SEC Rule 10b5-1 . . ., that trade was immunized from any liability." (Wadekar Mem. of Law 29-30.) However, 17 C.F.R. § 240.10b5-1(c)(1)(ii) provides that

and that Deka purchased 61,076 shares that same day (Ex. C to the Decl. of Christopher S. Hinton in Supp. of the Mot. of Deka Ireland for Consolidation, Appointment as Lead Pl. and Approval of Lead Pl.'s Selection of Lead Counsel). As such, Plaintiff has alleged that Wadekar and Shah traded contemporaneously with Deka. Therefore, the motions to dismiss this count will be denied.

F. Controlling Person Liability

The fifth count in the Complaint alleges a violation of § 20(a) of the Exchange Act as to all of the defendants. Section 20(a) provides that

> [e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a).

In order to state a claim under this section, "[p]laintiffs must plead facts showing: (1) an underlying violation by the company; and (2) circumstances establishing defendant's control over the company's actions. . . . 'To establish that a defendant is a control person, a plaintiff must demonstrate [that] 'the defendant had actual power or influence over the allegedly controlled''company." Jones v. Intelli-Check, Inc., 274 F. Supp. 2d 615, 644-45 (D.N.J. 2003)

"Paragraph (c)(1)(i) of this section is applicable only when the contract, instruction, or plan to purchase or sell securities was given or entered into in good faith and not as part of a plan or scheme to evade the prohibitions of this section." Therefore, a 10b5-1 trading plan does not provide an absolute defense to a claim of insider trading. Rather, it requires an additional factual finding of good faith. Not only can this Court not make such factual findings when considering a motion to dismiss, but this Court must also draw all inferences in favor of the non-moving party. Therefore, this Court cannot infer that Wadekar acted in good faith in adopting his 10b5-1 plan. The trade cannot be immunized from liability.

(internal citations omitted) (quoting In re MobileMedia Sec. Litig., 28 F. Supp. 2d 901, 940 (D.N.J. 1998)). "[I]t is well-settled that controlling person liability is premised on an independent violation of the federal securities laws." In re Rockefeller Ctr. Prop., 311 F.3d at 211.

All defendants argue that Plaintiff has failed to plead an underlying violation of the securities law by Able. Additionally, Klemick, Boehm, Mauro, and Shah argue that the Complaint fails to allege they were controlling persons. Finally, in a single sentence, Mauro and Boehm argue that the Complaint fails to allege culpable participation on their part.

Plaintiff has pled sufficiently a violation of § 10(b). "[T]here is no requirement in the language of [the] statute that the controlled person be named as a defendant as a predicate to imposing liability upon the controlling individual defendants. A plaintiff need only establish the controlled person's liability." Suprema, 438 F.3d at 285.

Here, as in Suprema, the controlled person – the company – is in bankruptcy and is not named as a defendant. So long as the complaint alleges violations by Able, the first prong of the test will be met. Count I of the Complaint alleges in detail that the Company, along with Wadekar, Mauro, and Shah, acted in violation of Rule 10b-5(b) by making untrue statements in earnings conference calls, on various SEC forms, and in various press releases. (Am. Comp. ¶ 201.) These specific allegations suffice to demonstrate an underlying violation of the securities acts by Able. See Suprema, 438 F.3d at 286.

As to the question of whether or not Klemick, Boehm, Mauro, and Shah controlled Able, all that is required in order to survive a motion to dismiss, pursuant to FED. R. CIV. P. 12(b)(6), is an allegation, not proof, that these individuals were controlling persons. That is, in evaluating a

motion to dismiss, the court is required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party.[41] Oshiver, 38 F.3d at 1384. Each of the defendants argues that the duties described in the Complaint and attributed to them are insufficient to show control.[42] To the contrary, the Complaint specifically makes such an allegation with respect to each of the individual defendants. (See Am. Compl. ¶¶ 246-54.) While the defendants attempt to introduce

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[41] While the Third Circuit has not explicitly stated so, that court has not disturbed the holding of a district court that concluded that "[t]he heightened pleading requirements of Rule 9(b) do not apply to claims under Section 20(a). 'Allegations that support a reasonable inference that [defendants] had the potential to influence and direct the activities of the primary violator suffice to plead control person liability.'" In re Royal Dutch/Shell Transp. Sec. Litig., 380 F. Supp. 2d 509, 565 (D.N.J. 2005) (quoting In re U.S. Interactive, Inc. Class Action Sec. Litig., No. 01-CV-522, 2002 WL 1971252, *18 (E.D. Pa. Aug. 23, 2002)). As such, Plaintiff is not required to plead specific facts in support of its allegations.

[42] During oral argument, counsel for Klemick vigorously argued that Klemick never held a position with sufficient authority to exercise control over Able. (See, e.g., Tr. 10:7-11:6, 12:2-13:18, 17:23-18:10.) This Court disagrees. The Complaint alleges that Klemick was "Director of Regulatory Affairs until April 2005, and [w]as Vice President of Compliance thereafter. In both positions, Klemick was responsible for ensuring the Company's compliance with FDA regulations. . . . [She] had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Able, including its quality control function and/or the content and dissemination of the false or misleading statements complained of herein. . . . During Klemick's tenure at Able, the Company was wholly deficient in its compliance with FDA requirements for cGMP and Klemick was alerted to these problems no later than April 2004 with the issuance of the FDA's warning letter. Under Klemick's watch, however, the Company continued to violate FDA regulations, failed to address the deficiencies in quality controls that the FDA identified, and concealed known quality control problems from investors. In December 2004, when Shah, Klemick's immediate supervisor, was forced to resign from his position as Vice President of Quality and Regulatory, Able's quality control failures were made even more evident to Klemick. Yet, she permitted Able to continue to mislead[] investors about its compliance with FDA regulations. As such, Klemick was a culpable participant in Able's fraudulent conduct." (Am. Compl. ¶¶ 249, 250, 252.) Drawing all inferences in favor of Plaintiff, these allegations demonstrate that Klemick had control over Able's FDA reporting and compliance, which form the crux of the alleged violations. This Court concludes that the Complaint sufficiently alleges that Klemick was a controlling person.

factual assertions regarding the actual effect of their respective duties, this Court cannot consider additional factual allegations without converting the motion to dismiss into a motion for summary judgment. See FED. R. CIV. P. 12(b). No such conversion shall take place here.

Defendants also claim that the controlling person claim fails since the Complaint does not allege that the defendants were "culpable participants" in the fraud. However, the Third Circuit does not require that culpable participation be pled in order to establish controlling person liability.[43] As a consequence, the majority of the judges in the District of New Jersey addressing the issue have concluded, and this Court agrees, that culpable participation need not be pled in order to state a claim for controlling person liability, see, e.g., In re Campbell Soup Co. Sec. Litig., 145 F. Supp. 2d 574, 600 (D.N.J. 2001).

In Rochez Bros., Inc. v. Rhoades, 527 F.2d 880 (3d Cir. 1975), the Third Circuit concluded that "Congress intended that the element of culpability be proven to impose liability on a securities law violator." Rochez, 527 F.2d at 889-90. The key phrase in this quote is "be proven" – unlike the present case which involves a motion to dismiss, the Rochez case had been tried to conclusion. The district courts in New Jersey have interpreted this requirement in

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[43] During oral argument, counsel argued, based on a single sentence in Suprema, that culpable participation is indeed a pleading requirement in the Third Circuit. The Third Circuit has not held that a plaintiff needs to plead culpable participation; however, in Suprema, the court did conclude that "[t]he complaints also detailed the manner in which [the individual defendants] are alleged to have tightly controlled Suprema's business and operations and acted as culpable participants in the fraud." Suprema, 438 F.3d at 286. Prior to this conclusion, when the court set forth the standard for a § 20(a) claim, there is no mention of culpable participation, only the statement that "the plaintiff must prove that one person controlled another person or entity and that the controlled person or entity committed a primary violation of the securities laws." Suprema, 438 F.3d at 284. This Court is not persuaded that the Third Circuit would, through a single, conclusory sentence, change a 33-year-old precedent. However, even if pleading culpable participation was a requirement, Plaintiff did so allege. (Am. Compl. ¶¶ 251-53.)

varying ways.

In Jones v. Intelli-Check, Judge Wolfson cites a 1996 case that holds that "the 'overwhelming trend in this circuit' is that culpable participation does not have to be plead [sic] in order to survive a motion to dismiss." Jones v. Intelli-Check, 274 F. Supp. 2d at 645 (citing Derensis v. Coopers & Lybrand Chartered Accountants, 930 F. Supp. 1003, 1013 (D.N.J. 1996)).

However, Judge Lechner, relying on a Second Circuit case, stated that "[i]n order to maintain a cause of action for control person liability under Section 20(a), a plaintiff is required to establish: (1) an underlying violation by a controlled person or entity; (2) that the defendants are controlling persons; and (3) that they were in some meaningful sense culpable participants in the fraud." In re Nice Systems, 135 F. Supp. 2d at 588. This view has not garnered any additional adherents.

On the other hand, Judge Irenas concluded in In re Campbell Soup that plaintiffs need not allege culpable participation at the pleading stage. 145 F. Supp. 2d at 599-600. Similarly, in Derensis, 930 F. Supp. 1003 (D.N.J. 1996), Judge Bassler concluded that plaintiffs "'need only plead circumstances establishing control because: (1) the facts establishing culpable participation can only be expected to emerge after discovery; and (2) virtually all of the remaining evidence, should it exist, is usually within the defendants' control.'" Id. at 1013 (quoting Easton & Co. v. Mut. Benefit Life Ins. Co., No. 91-CV-4012 (HLS), 1992 WL 136857, at *6 (D.N.J. Mar. 29, 1992)).

This Court finds that Judge Wolfson's, Judge Irenas's, and Judge Bassler's reasoning is not only a logical interpretation of the Rochez decision, but also sensible. Therefore, plaintiffs need not plead culpable participation. As a result, Plaintiff in this case has pled sufficiently a

claim of controlling person liability on the part of Wadekar, Klemick, Boehm, Mauro, and Shah, and the motions to dismiss this count will be denied.

V. Conclusion

As discussed above, Plaintiff has alleged scienter sufficiently, based on recklessness, on the part of Wadekar, Mauro, and Shah; therefore, the motions to dismiss Count I of the Complaint, which alleges violations of Rule 10b-5(b) by Wadekar, Mauro, and Shah, will be denied. The motions to dismiss Count II of the Complaint, which alleges violations of Rule 10b-5(a) and (c), will also be denied since Plaintiff adequately alleges both scienter and specific instances of manipulative and deceptive conduct on the part of Shah and Wadekar. The motion to dismiss Count III, the Section 18 claim against Wadekar, will be denied since Plaintiff alleges actual reliance on specific statements. The motions to dimiss Count IV, the insider trading claim against Wadekar and Shah, will be denied since Plaintiff alleges an underlying violation of the securities laws and a contemporaneous trade by each defendant. The motions to dismiss Count V, the control person claim against Wadekar, Mauro, Shah, Boehm, amd Klemick, will be denied since Plaintiff alleges an underlying violation of the securities laws and control by each defendant

Dated: March 24, 2008

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREENAWAY, JR., U.S.D.J.