

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: DISCOVERY LABORATORIES : MASTER FILE NO.
SECURITIES LITIGATION : 06-1820
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MEMORANDUM

Dalzell, J.

November 1, 2006

This case, as well as the related shareholder derivative suit before us in C.A. No. 06-2058, arises out of the collapse of Discovery Laboratories' stock price in the wake of problems with the manufacture of its flagship product, Surfaxin. Plaintiffs, a putative class consisting of Discovery stockholders, allege that defendants made false and misleading statements in connection with the sale of securities in violation of the Securities Exchange Act of 1934 ("the '34 Act"). In addition to Discovery itself, plaintiffs are seeking damages against two officers of the company, Robert Capetola, President and CEO, and Christopher Schaber, former Executive Vice-President and COO.

Facts

Discovery is a small biotechnology company that focuses on the production of remedies for respiratory diseases. In particular, Discovery develops therapies to replace natural surfactants, which are essential to the lungs' ability to absorb oxygen. Although Discovery currently has no product on the market, its leading candidate is a synthetic surfactant, Surfaxin, which would be used in the prevention and treatment of

Respiratory Distress Syndrome (RDS) in premature infants. According to the complaint, some other companies have surfactant products currently on the market that are primarily animal-derived rather than synthetic. Discovery's stock trades on the NASDAQ National Market under the symbol DSCO.

In April, 2004, Discovery filed a New Drug Application (NDA) with the United States Food and Drug Administration (FDA). In October, 2004, it filed a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMA), the FDA's counterpart in the European Community. Both applications were supported by two Phase 3 clinical trials: the SELECT trial, which demonstrated that Surfaxin was more effective in treating RDS than Exosurf, another synthetic surfactant; and the STAR trial, which demonstrated that Surfaxin was no less effective than Curosurf, a pig-derived surfactant that is the most commonly used treatment in Europe. In the process of designing these trials, Discovery had received conflicting advice from the FDA and the EMA about the nature of the trials. Because the FDA's clinical guidance was binding whereas the EMA's was merely advisory, and because the company lacked the resources to perform the trials both agencies suggested, it elected to follow the FDA's proposed clinical format in hopes of obtaining both approvals.

In addition to the clinical trials, Discovery was required to demonstrate its ability to manufacture Surfaxin in compliance with the FDA's current Good Manufacturing Practices (cGMP). Because Discovery lacked manufacturing facilities of its

own, it needed to associate with a contract manufacturer. In August, 2003, Discovery announced that it had selected Laureate Pharma L.P, an affiliate of Purdue Pharma L.P., to be its manufacturing partner. In October, the two companies announced an agreement to manufacture Surfaxin at Laureate's Totowa, New Jersey facility. The manufacturing agreement contemplated the manufacture of Discovery's product on dedicated machinery that Discovery would provide.

The Totowa facility had previously been operated by Purdue itself and by another of its affiliates, P.F. Labs. Both Purdue and P.F. Labs had encountered compliance difficulties at the site, receiving between them a series of FDA Form 483 reports and two warning letters related to their compliance with cGMP. The second and final warning was issued to Purdue in 2001.

On February 27, 2004, Capetola entered into a variable prepaid forward contract (VPFC) to sell some of his shares of Discovery stock. The contract, which paid him \$4,774,639.59, required him to deliver between 377,825 and 472,269 shares of Discovery stock on February 27, 2006. On March 18, 2004, Capetola entered into another VPFC, obligating him to deliver between 230,784 and 300,000 shares of Discovery on March 18, 2007. That contract paid him \$3,159,000. On April 7, 2004, Schaber entered into a VPFC to deliver between 171,562 and 205,820 shares of Discovery on April 7, 2006, and he received \$2,311,359 in the transaction.

As part of its review of the Surfaxin NDA, the FDA conducted an inspection of the Totowa facility. On January 21,

2005, the inspection team issued a Form 483 to Laureate identifying some problems with the facility's cGMP compliance. On February 1, Discovery issued a press release announcing that it had received the Form 483 and outlining its plans to fix the problems the FDA identified. Over the next several months, Discovery began making plans to manage the Totowa facility itself and began hiring executives with expertise in manufacturing and quality control.

In February, 2005, Discovery received an approvable letter from the FDA, stating that approval of Surfaxin would occur once specific conditions were met. Approval of the Surfaxin NDA was now dependant on finalizing the product's labeling and remedying the compliance problems at the Totowa facility. On July 29, 2005, Discovery filed its response to the approvable letter, identifying the steps it was taking to address the FDA's concerns. In August of 2005, the FDA responded, first verbally and then in writing, that it did not consider Discovery's response to the approvable letter complete. In October, Discovery filed a revised response.

On November 3, 2005, Discovery announced that it was taking steps to acquire the Totowa facility. In December, the company entered into an agreement with Laureate to assume the existing lease, retain much of the staff, and take over its own manufacturing operations.

On April 5, 2006, Discovery announced that it had received a second approvable letter from the FDA requiring additional remediation before Surfaxin would be approved. On

April 24, 2006, the company announced that some of its process validation batches¹ had failed stability testing.² This meant a potentially significant delay in approval. On May 4, 2006, the company announced it had fired Schaber and that the executives in charge of manufacturing and quality control would now report directly to Capetola.

Finally, on June 6, 2006, citing problems with manufacturing and stability, Discovery withdrew its MAA from consideration by the EMEA. Neither the FDA nor the EMEA have yet approved Surfaxin.

Statements at Issue

Plaintiffs have alleged many false and/or misleading statements during the putative class period.³ Because we must determine which, if any, of these statements have been alleged with the requisite specificity, we must first rehearse the over two dozen listed in the consolidated amended complaint.⁴

¹ These are batches of drug product that are provided to the FDA for validation and testing. See 21 C.F.R. § 820.3(z)(1).

² Stability testing measures a drug's shelf life.

³ The class period runs from March 15, 2004, the date that Discovery filed its 2003 Form 10-K, to June 6, 2006, the date Discovery withdrew its MAA.

⁴ The PSLRA requires plaintiffs to "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Because of this, we need only consider statements that the complaint specifically contends are false or misleading. We will identify each statement by the paragraph in the complaint in which it is quoted.

Statement 64: In its 2003 Form 10-K, Discovery stated: "We recently completed two Phase 3 clinical trials of Surfaxin®, our lead product, for the treatment of Respiratory Distress Syndrome in premature infants and are preparing to file new drug applications with the United States Food and Drug Administration and other regulatory agencies in the rest of the world." Compl. ¶ 64. Plaintiffs allege that this was false or misleading because it failed to mention that the trials were conducted under protocols discussed with the FDA but not approved by the EMEA. Compl. ¶ 69a.

Statement 65: Also in the 2003 10-K, Discovery announced that it was implementing a strategy including "manufacturing for the production of our humanized surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfaxin, if approved, in the U.S. and in Europe." Compl. ¶ 65. Plaintiffs allege that this was false or misleading because it failed to mention that the trials were conducted under protocols discussed with the FDA, but not approved by the EMEA, and because Discovery had failed to disclose the previous cGMP compliance problems at the Totowa facility. Compl. ¶ 69b.

Statement 66: In the 2003 10-K, Discovery also said "we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life." Compl. ¶ 66. Plaintiffs claim that this statement was false or misleading

because Discovery "had not conducted sufficient stability testing under [cGMP] to support it." Compl. ¶ 69c.

Statement 67: Finally, the 2003 10-K said: "All steps required for production of cGMP material have been completed and we are presently producing Surfaxin for our Phase 2 trial for the treatment of Acute Respiratory Distress Syndrome." Compl. ¶ 67. Plaintiffs contend that this statement was false or misleading because Discovery had not disclosed the Totowa facility's history of regulatory problems or the fact that the Totowa facility had never been used to commercialize a product. Compl. ¶ 69d.

Statement 70: On March 16, 2004, Discovery stated in a press release that it had entered into an agreement with Laureate and that "[a]ll steps required for the production of material in conformance with current Good Manufacturing Practices (cGMPs) have been completed." Compl. ¶ 70. Plaintiffs allege that this is false or misleading because Discovery had not disclosed the Totowa facility's history of regulatory problems. Compl. ¶ 71.

Statement 72: In the same press release, Discovery announced the results of its successful Phase 3 trials and stated: "We intend to use the results from these trials to form the basis for a new drug application (NDA) with the [FDA] as well as for regulatory applications for approval in the rest of the world." Compl. ¶ 72. Plaintiffs contend this statement is misleading because Discovery knew that its Phase 3 trials were not sufficient to meet EMEA clinical requirements.

Statement 79: On May 6, 2004, Discovery issued a press release announcing the submission of its NDA to the FDA. It

continued: "The Company is also preparing [an MAA] to be filed with the [EMEA] by the middle of 2004." Compl. ¶ 79. Plaintiffs contend this is false or misleading because defendants knew that the Phase 3 protocols had not been approved by the EMEA and that the studies did not satisfy EMEA clinical requirements. Compl. ¶ 80.

Statement 81: In that same press release, Discovery announced that it had "completed all steps required for the production of [Surfaxin] in conformance with [cGMP]" at Laureate. Compl. ¶ 81. Plaintiffs allege this was false and misleading because Discovery had not disclosed the Totowa facility's history of regulatory problems. Compl. ¶ 82.

Statement 85: In a June 15, 2004 press release, Discovery announced that the FDA had accepted its NDA filing and had "established a target date of February 13, 2005 for completion of review of the Surfaxin NDA." Compl. ¶ 85. Plaintiffs allege that this is false and misleading because approval of the NDA was dependent on Discovery's ability to comply with cGMP and because the company had not disclosed the Totowa facility's history of regulatory problems. Compl. ¶ 87.

Statement 86: The same press release continued: "Discovery is also preparing [an MAA] to be filed with the [EMEA] in the second half of 2004 for Surfaxin for the prevention and treatment of RDS." Compl. ¶ 86. Plaintiffs claim this statement was false or misleading because it "failed to disclose the fact that the Phase 3 clinical trials for Surfaxin® had not been designed to comply with EMEA's clinical standards." Compl. ¶ 87.

Statement 91: On August 5, 2004, Discovery issued a press release that quoted Capetola as saying "Discovery now is focusing on preparing for the commercialization of Surfaxin® for Respiratory Distress Syndrome (RDS), if approved." Compl. ¶ 91. Plaintiffs allege that this is false and misleading because approval of the NDA was dependent on Discovery's ability to comply with cGMP and because the company had not disclosed the Totowa facility's history of regulatory problems. Id.

Statement 92a: In that same release Discovery said: "The FDA has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA."⁵ Compl. ¶ 92. Plaintiffs allege that this is false and misleading because approval of the NDA was dependent on Discovery's ability to comply with cGMP and because the company had not disclosed the Totowa facility's history of regulatory problems. Compl. ¶ 93.

Statement 92b: Also in the same release, Discovery said: "The Company is also preparing [an MAA] to be filed with the [EMEA] in the second half of 2004 for Surfaxin for the prevention and treatment of RDS."⁶ Compl. ¶ 92. Plaintiffs claim this statement was false or misleading because it failed to disclose that the Phase 3 clinical trials had not been designed to comply with the EMEA's clinical standards. Compl. ¶ 93.

Statement 94: In its August 9, 2004 Form 10-Q, Discovery announced that it had "established a Surfaxin

⁵ This statement is identical to statement 85.

⁶ This statement is identical to statement 86.

manufacturing line to support the production of clinical and commercial drug supply in conformance with [cGMP]." They went on to state that the manufacturing line could provide material both for the "commercial-scale requirements of Surfaxin" in infants and the ongoing Phase 2 clinical trials in adults. Compl. ¶ 94. Plaintiffs allege the statement was false or misleading because Discovery had not disclosed the Totowa facility's history of regulatory problems or the fact that the Totowa facility had never been used to commercialize a new product.

Statement 97: On October 27, 2004, Discovery issued a press release announcing that its MAA was complete and the EMEA would begin review. The announcement noted that the MAA was "supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials." Compl. ¶ 97. Plaintiffs allege that this statement is misleading because Discovery failed to disclose that the trials had not been designed to meet EMEA clinical standards. Compl. ¶ 98.

Statement 100: On November 4, 2004, Discovery issued a press release that quoted Capetola as saying "[o]ur proprietary surfactant technology represents a new paradigm that we believe will revolutionize the treatment of respiratory diseases. For the first time, medical practitioners in the NICU can envision surfactant products that are precisely engineered to address various life-threatening respiratory diseases -- and a company capable of fulfilling a commitment to this community." Compl. ¶ 100. Plaintiffs contend this statement was false or misleading because the company had not disclosed the Totowa facility's

history of regulatory problems and because it faced the risk that it "lacked the manufacturing capability to bring Surfaxin® to market." Id.

Statement 101: On the same day, Discovery issued a press release reporting the results for its third quarter operations. The press release described a number of steps the company had taken "to enhance the commercial and medical value of our Surfactant Replacement Therapies, beginning with the potential launch of Surfaxin which is currently under review by the FDA and the [EMEA]." Compl. ¶ 101. Plaintiffs allege that this was false or misleading because it failed to mention that the trials were conducted under protocols discussed with the FDA, but not approved by the EMEA, and because Discovery had failed to disclose the risk that it would be unable to manufacture Surfaxin in compliance with cGMP. Compl. ¶ 102.

Statement 103a: In its November 9, 2004 Form 10-Q, Discovery said: "We have filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin." Compl. ¶ 103. Plaintiffs claim this statement was false or misleading because the company failed to disclose that its Phase 3 trials were not designed to meet EMEA's clinical standards. Id.

Statement 103b: The 10-Q also declared: "We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to

execute the launch of Surfaxin, if approved, in the U.S. and Europe." Id. Plaintiffs contend this statement was false or misleading because the company had not disclosed the Totowa facility's history of regulatory problems. Id.

Statement 104: The 10-Q also stated that Discovery had "established a Surfaxin manufacturing line to support the production of clinical and commercial drug supply in conformance with [cGMP]." It went on to say that the manufacturing line could provide material both for the "commercial-scale requirements of Surfaxin" in infants and the ongoing Phase 2 clinical trials in adults.⁷ Compl. ¶ 104. Again, plaintiffs contend this statement was false or misleading because the company had not disclosed the Totowa facility's history of regulatory problems. They also claim that Discovery failed to disclose that the Totowa facility was undergoing a change of control. Id.

Statement 118a: In its 2004 Form 10-K, which was released on March 16, 2005, Discovery stated "[w]e believe that our precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants." Compl. ¶ 118. Plaintiffs claim this statement is false or misleading because defendants did not yet

⁷ Except for slight modification of the language describing the clinical trials in adults -- which had by this time progressed to a later stage -- this statement is identical to statement 94.

have a facility capable of manufacturing Surfaxin in compliance with cGMP. Compl. ¶ 119.

Statement 118b: Also in its 2004 10-K, Discovery said "we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life."⁸ Compl. ¶ 118. Plaintiffs allege that this is false and misleading because Discovery "had not conducted sufficient stability testing under [cGMP] to support it." Compl. ¶ 119.

Statement 120: In the same 10-K, Discovery announced that it had received an approvable letter from the FDA and identified the conditions on Surfaxin's approval. The company went on to say, "[a]ssuming the adequacy of such corrective actions and the approval of marketing clearance for Surfaxin, we anticipate that the potential approval and commercial launch of Surfaxin for the United States will occur in the first quarter of 2006." Compl. ¶ 120. Plaintiffs assert that this statement was false or misleading because of the Totowa facility's history of regulatory problems and because the company "lacked sufficient personnel with relevant expertise to remediate the Totowa facility." Compl. ¶ 121.

Statement 122: The 10-K also reported that the EMEA had validated the Surfaxin MAA and had begun its review process. The company concluded, "[w]e anticipate the potential approval of Surfaxin for Europe will occur in the first quarter of 2006."

⁸ This statement is identical to statement 66.

Compl. ¶ 122. Plaintiffs allege that this statement was false and misleading because the company had not disclosed that the Phase 3 trials had not been designed to meet EMEA's clinical standards. Id.

Statement 123: On April 27, 2005, Discovery issued a press release on the status of its remediation efforts. The document concluded, "we remain on schedule to submit a Complete Response Letter to the FDA by July 2005. Our organization is committed to the anticipated commercial launch of our first precision-engineered surfactant product in the first quarter of 2006." Compl. ¶ 123. Plaintiffs contend this statement was misleading because Discovery lacked personnel with the proper expertise to remediate the Totowa facility. Compl. ¶ 124.

Statement 126: In its May 4, 2005 Form 10-Q, Discovery reiterated that "[w]e anticipate potential approval and commercial launch of Surfaxin in the United States and potential EMEA approval to occur in the first quarter of 2006." Compl. ¶ 126. Plaintiffs claim this statement is false and misleading because the company failed to disclose that the Phase 3 trials had not been designed to meet EMEA's clinical standards. Id.

Statement 127: The May 4 10-Q addressed the manufacturing remediation by saying: "We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of its cGMP Action Plan dated January 31, 2005, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants and all of our

anticipated clinical-scale production requirements...." Compl. ¶ 127. Plaintiffs assert that this statement was false or misleading because of the Totowa facility's history of regulatory problems and because the company "lacked sufficient personnel with relevant expertise to remediate the Totowa Facility." Compl. ¶ 128.

Statement 132: Discovery's press release of August 2, 2005, reporting its second quarter results, said that "[w]e believe that we are well positioned as a company based on the potential U.S. launch and European approval of Surfaxin in the first quarter of 2006." Compl. ¶ 132. Plaintiffs claim this statement is false and misleading because the company failed to disclose that the Phase 3 trials had not been designed to meet EMEA's clinical standards. Id.

Statement 134: Discovery's August 5, 2005 Form 10-Q filing included the statement that "we have filed [an MAA] with the [EMEA] for clearance to market Surfaxin in Europe." Compl. ¶ 134. Again, plaintiffs take issue with this statement because the Phase 3 trials had not been designed to meet EMEA's clinical standards. Id.

Statement 135: In the August 5 Form 10-Q, Discovery also stated that "[w]e believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support this response prepare us for the FDA's reinspection of Laureate's Totowa facility." Compl. ¶ 135. Plaintiffs contend this statement is false or misleading because "defendants were not in fact satisfied with the remediation

efforts at the Totowa Facility and were working to obtain direct control over it." Compl. ¶ 136.

To simplify our analysis, we note that there are several common themes running through plaintiffs' allegations. Nearly all of the statements fall into one or more of six categories.

Four of the statements⁹ are alleged to be false and misleading because Discovery had not disclosed that the EMEA had not approved its Phase 3 protocols. We will refer to these statements as the "EMEA protocol" statements.

Ten of them¹⁰ are alleged to be false and misleading because plaintiffs claim that Discovery knew, but did not disclose, that its Phase 3 protocols did not meet EMEA clinical standards. We will refer to these statements as the "EMEA standards" statements.

Thirteen of the statements¹¹ are alleged to be false and misleading because Discovery had not disclosed past problems at the Totowa facility.¹² We will refer to these as the "Totowa"

⁹ Statements 64, 65, 79, and 101.

¹⁰ Statements 72, 79, 86, 92b, 97, 103a, 122, 126, 132, and 134.

¹¹ Statements 65, 67, 70, 81, 85, 91, 92a, 94, 100, 103b, 104, 120, and 127.

¹² Defendants present much evidence in support of their contention that Discovery Labs' contract manufacturing facility, the Laureate Totowa facility, is not the same as the P.F. Labs Totowa facility to which the violation letters were issued. While it is true that the evidence is generally of the form that we would be permitted to take judicial notice of in a motion to dismiss, see In re NAHC, Inc. Sec. Litiq., 306 F.3d 1314, 1331

(continued...)

statements.

Two of them¹³ are alleged to be false and misleading because Discovery had not yet performed adequate stability testing to support those statements. Those we will refer to as the "stability" statements.

Four of the statements¹⁴ are alleged to be false and misleading because Discovery had not disclosed the risk that it might be unable to comply with cGMP and might, therefore, be unable to commercialize Surfaxin. We will refer to these as the "cGMP" statements.

Finally, three of the statements¹⁵ are alleged to be false and misleading because Discovery lacked the manufacturing expertise to fix the problems at the Totowa plant. We will refer to these as the "expertise" statements.

¹²(...continued)
(3d Cir. 2002), because we must construe the complaint in the light most favorable to plaintiffs, we cannot discount these statements on that basis. Although it appears, as defendants contend, that the two facilities were under different management and would have been considered by the FDA to be unrelated, it is not so clearly evident that we can say with certainty that dismissal of the claims is warranted on those grounds. Thus, we will assume, for purposes of this motion only, that the Form 483 reports and warning letters at issue were issued to the same facility that was manufacturing Surfaxin.

¹³ Statements 66 and 118b.

¹⁴ Statements 85, 91, 92a, and 101.

¹⁵ Statements 120, 123, and 127.

There are also statements¹⁶ about which plaintiffs make unique allegations that these categories do not cover. We will deal with these statements individually where appropriate.

With these classifications in hand, we move on to our analysis.

Legal Analysis

Plaintiffs allege that defendants made or failed to make statements in violation of Section 10(b) of the '34 Act, codified as amended at 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5. "To state a claim for relief under section 10(b), a plaintiff must plead facts demonstrating that (1) the defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading; (2) the defendant acted with scienter; and (3) the plaintiff's reliance on the defendant's misstatement caused him or her injury."¹⁷ Cal. Pub. Employees' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 143 (3d Cir. 2004). Claims brought under Section 10(b) and Rule 10b-5 must meet the heightened pleading requirements of Fed. R. Civ. P. 9(b) and the specific requirements of 15 U.S.C. § 78u-4(b), which is a portion of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). In

¹⁶ Statements 67, 94, 100, 104, 118a, and 135.

¹⁷ Defendants do not challenge reliance or causation in their motion. With regard to public statements and publicly traded securities, courts apply a "fraud-on-the-market" theory, which assumes that the market price of the securities incorporates any alleged misrepresentations and therefore reliance and causation may be assumed for all investors. See Basic, Inc. v. Levinson, 485 U.S. 224, 241-43 (1988).

spite of these heightened pleading requirements, however, even in a securities fraud case "[a] motion to dismiss pursuant to Rule 12(b)(6) may be granted only if, accepting all well pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997). Thus, we may grant defendants' motion only if, viewing the complaint in the light most favorable to the plaintiffs, no statement can be identified that meets the requirements of the '34 Act, Rule 9(b), and the PSLRA.

False or Misleading Statements

We must first assess whether the statements alleged were, in fact, false or misleading. "A statement is false or misleading if it is factually inaccurate, or additional information is required to clarify it." Wallace v. Sys. & Computer Tech. Corp., 1997 WL 602808, at *9 (E.D. Pa. Sept. 23, 1997). Plaintiffs do not allege, nor does it appear to be the case, that any of the statements at issue were actually false at the time they were made. Failure to disclose a fact, however, can lead to liability under Rule 10b-5 "where silence would make other statements misleading or false." Id. Thus, the allegations here arise from defendants' alleged failure to disclose facts necessary to clarify their otherwise (at least technically) accurate statements of fact.

In order to state a claim, then, plaintiffs must, at a minimum, allege the existence of some fact, known to defendants

at the time of the statements,¹⁸ whose disclosure would have made the statement clearer or more correct. They must also demonstrate that, without this additional fact, a reasonable investor was likely to be misled by the statement. It is not enough simply to show that there is additional information defendants could have provided that would have made the statement clearer. Plaintiffs must also show that, in the absence of that clarification, there was a substantial danger that investors would be misled.

With regard to the EMEA protocol statements, plaintiffs have failed to make this required showing. Unlike the FDA, the EMEA does not approve clinical protocols in advance. Although the EMEA may provide guidance or advice, EMEA clinical advice "is not binding for the EMEA or the applicant with regard to any future marketing authorisation application of the product concerned." Def. Br., Exh. 107 at 7 (excerpt from EMEA "Procedures for marketing authorisation"). Plaintiffs' claims that Discovery failed to disclose that the protocols were not approved in advance, where no such approval was possible, do not state a claim.

With regard to the Totowa statements, plaintiffs have not alleged that defendants were actually aware of the FDA Form 483 reports and the warning letters. Although they claim that "defendants had a duty to engage in due diligence," a failure to

¹⁸ In some circumstances, a plaintiff can successfully plead a securities fraud claim on the basis of defendants' reckless failure to acquire information. We address that theory in our discussion of scienter below.

fulfill a duty to the shareholders would support a derivative suit,¹⁹ not a securities fraud suit. Because plaintiffs have not claimed that defendants were aware of the information they allegedly withheld regarding the Totowa statements, such statements cannot sustain plaintiffs' Rule 10b-5 claims.

As for the stability statements, plaintiffs make only the blanket claim that Discovery had not "conducted sufficient stability testing" to support those statements. Plaintiffs make no allegations regarding the stability testing that Discovery did or did not conduct prior to those statements. They apparently ask us to infer from the fact that stability subsequently was identified as a problem that defendants had not performed adequate testing. But this is the very essence of fraud by hindsight. An omission "that is misleading only in hindsight" cannot form the basis for a securities fraud claim. Zucker v. Quasha, 891 F.Supp. 1010, 1017 (D.N.J. 1995) (aff'd 82 F.3d 408 (3d Cir. 1996)). Because plaintiffs have not alleged any facts known to defendants that they withheld, they have failed to adequately plead a securities fraud claim based on the stability statements.

A similar defect exists with the expertise statements. Although plaintiffs claim that Discovery lacked the necessary expertise to remediate the problems at the Totowa facility, the only basis for their claim appears to be that the remediation was ultimately unsuccessful. Plaintiffs have not alleged that anyone

¹⁹ Such a suit has been filed and is currently before this Court.

at Discovery was aware that they lacked sufficient expertise to complete the remediation plan successfully. Indeed, plaintiffs would need to allege not only that Discovery knew it lacked the relevant expertise, but also that it knew that Laureate, its contract manufacturer upon whom it would reasonably depend for advice on manufacturing issues, lacked the relevant expertise. We cannot fairly infer such knowledge from the subsequent failure of remediation. Consequently, the expertise statements cannot form the basis for a securities fraud claim.

Materiality

Having established that at least some of plaintiffs' claims allege misleading omissions, we must now determine whether such alleged omissions were material. "An omitted fact is material if there is a 'substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder.'" Shapiro v. UJB Fin. Corp., 964 F.2d 272, 280 n.11 (3d Cir. 1992) (quoting TSC Indus. v. Northway, Inc., 426 U.S. 438, 449 (1976)). The important question is whether that information, if disclosed, "would have been viewed by the reasonable investor as having 'significantly altered the "total mix" of information' available to that investor." In re Westinghouse Sec. Litig., 90 F.3d 696, 714 (3d Cir. 1996) (quoting TSC, 426 U.S. at 449). Because the question of materiality is concerned with the "total mix" of information, "a statement or omission is materially misleading only if the

allegedly undisclosed facts have not already entered the market." Winer Family Trust v. Queen, 2004 WL 2203709 at *4 (E.D. Pa. Sept. 27, 2004).

With regard to the Totowa statements, defendants argue both that the information allegedly withheld would not be significant to a reasonable investor and that the information was already available in the marketplace. We find both arguments compelling.

We begin by noting that in March of 1998, in addition to the warning letter issued to P.F. Labs regarding its manufacturing at the Totowa facility, the FDA issued seventy other warning letters. See FDA, Archived Warning Letters Index, available at http://www.accessdata.fda.gov/scripts/wlcfm/indexdate_archive.cfm. Plaintiffs would have us hold that not only were those seventy-one companies required to disclose to their investors that the FDA issued those warning letters,²⁰ but any other company subject to the provisions of the '34 Act with whom they entered into a contract for services in the future would also be required to make such a disclosure. Such a holding would only serve to bury the material information public

²⁰ It seems incontrovertible that this information would be material to investors in the company who received the letters.

companies currently disclose²¹ in a flood of red herrings. Such a result would scarcely protect investors.

Second, we note that this is not the sort of information that would form the basis for a reasonable investment decision. As we noted above, in a highly regulated industry, warnings such as those P.F. Labs received are a reality of doing business. Problems encountered in the manufacture of another company's product on different machinery in the same facility do not change the total mix of information available to a reasonable investor. In an attempt to prove otherwise, plaintiffs note that, on February 1, 2005, when Discovery Labs disclosed that the FDA had issued a Form 483 report on its manufacturing process, the stock dropped over twenty percent. See Pl. Br. at 43. Plaintiffs apparently hope that we will not notice the categorical difference in materiality to Discovery's investors between problems in the manufacture of Discovery's flagship product and problems in the manufacture of another company's product in the same facility seven years earlier.

Finally, we stress that these warning letters are publicly available. Indeed, the complaint itself notes that the warning letters and Form 483 reports given in 1998 and 2001 at the Totowa facility "were readily available to defendants from

²¹ As it is, the press releases and SEC filings produced by Discovery during the three-year period relevant to this matter comprise nearly four inches of paper, printed on both sides. See Def. Br, Exhs. 1-76. We shudder to imagine the volume that would have been produced if Discovery were also required to report on the historical difficulties of each of its partners and suppliers.

the FDA." Compl. ¶ 49. As we noted above, prior public disclosure negates a finding that material information was withheld. "A motion to dismiss may be granted if 'the company's SEC filings or other documents disclose the very information necessary to make their public statements not misleading.'" Winer Family Trust, 2004 WL 2203709 at *4 (quoting Wallace, 1997 WL 602808, at *10).

Plaintiffs contend that although the information was publicly available, it was too difficult to find to qualify as adequate disclosure. Their claim is that "[t]ying the FDA Warning Letters to Discovery Labs requires an understanding of the factual intricacies and detailed internal structure of the Company's operations and its relationship with its contract manufacturer." Pl. Br. at 46. The so-called "truth on the market" defense does not require that any investor should be capable of finding the information and understanding its significance based on a single click for a simple Web search. We deal here with reasonable investors, those who we can assume exercise due investment diligence.²² When Discovery Labs announced its relationship with Laureate, and the FDA reported that allegedly troubled history of Laureate's facility,²³ that

²² Indeed, plaintiffs admit that they learned of the Form 483 reports from "a former analyst." Pl. Br. at 22. This is a concession to efficient markets that are quickly informed by specialists who make it their business to dig through publicly available sources to inform the investing community.

²³ If an investor would need to understand the relationship of Laureate to Purdue and P.F. Labs in order to find the warning letters, that only supports defendants' contention
(continued...)

was sufficient public disclosure to allow us to invoke an assumption that the stock price reflected any adjustment in corporate value Discovery's new relationship caused.

For all these reasons, we find that the Totowa statements were not materially misleading.

Similarly, we find that the facts required to make the cGMP statements not misleading would have been known to a reasonable investor. Plaintiffs argue, in essence, that Discovery had a duty to disclose that, if it failed to comply with FDA regulations, the FDA would not approve the sale of Surfaxin. That should be obvious to a reasonable investor. The regulations are published in the Code of Federal Regulations, which is certainly publicly available. Once Discovery disclosed that it was awaiting approval from the FDA, it did not have a duty to further disclose that such approval would require compliance with published agency regulations. Thus, the cGMP statements were not materially misleading.

With regard to the EMEA standards statements, materiality is also at issue. Plaintiffs do not allege, nor could they, that defendants knew for certain that the EMEA would not approve Surfaxin based on the SELECT and STAR trials. Instead, they argue that defendants were required to reveal that

²³(...continued)
that the warning letters were issued to another entity entirely. Although at each level of remove from Discovery Labs' announcement the information becomes more difficult to uncover, its relevance to Discovery Labs investors likewise diminishes. We find that, if the prior warnings were relevant, sufficient public information was available to allow a prudent investor readily to find them.

the protocols they had selected did not meet EMEA clinical standards.

Plaintiffs do not, however, identify any specific "clinical standard" the EMEA promulgated with which the Surfaxin clinical trials failed to comply. Instead, they base their claim on the fact that Discovery declined to follow the clinical advice the EMEA provided. Plaintiffs apparently do not want to acknowledge that, unlike FDA clinical review, EMEA clinical advice "is not binding for the EMEA or the applicant with regard to any future marketing authorisation application of the product concerned." Def. Br., Exh. 107 at 7. Thus, the decision not to follow EMEA advice did not mean that Discovery Labs was abandoning its hope of marketing Surfaxin in Europe.²⁴ Indeed, it did not even mean that the EMEA would not approve Surfaxin without additional clinical data. Instead, the company was involved in a complex negotiation with two different agencies to design a clinical program it could afford to complete that would lead to approval by both the FDA and the EMEA. These negotiations were just the sort of "ongoing discussions" with regulatory agencies that the court in In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 966 (D. Md. 1995) found drug makers had no duty to disclose. Given the complexity of these negotiations,

²⁴ Plaintiffs' own brief describes the situation as follows: "approval would only occur if Discovery Labs was successful in convincing EMEA that it should rely upon the data that the FDA had accepted." Pl. Br. at 22. Given the current efforts underway to harmonize the approval processes in the U.S., Europe, and Japan, see Def. Br. at 20-22, this does not seem like the sort of situation that should lead shareholders to claim that Discovery behaved recklessly or fraudulently.

we agree with the Medimmune court that the law does not require blow-by-blow disclosures of conversations with regulatory agencies.

It is, to be sure, true that the EMEA eventually expressed some concerns about the overall clinical portfolio submitted for the MAA. See Def. Br., Exh. 101. First, although it is clear that Discovery was aware of clinical difficulties with the EMEA application in June of 2006, it is far from obvious that Discovery knew about these problems in March, 2004, when it made statement 64, the first of the EMEA approval statements. Second, Discovery and its executives continued to believe that they could obtain EMEA approval without doing additional clinical trials. Even in July of 2006, Capetola stated that he expected the EMEA would recognize the sufficiency of their clinical data and that "there are no new trials required." Def. Br., Exh. 81 at 18. But he noted that Discovery had no final word from the EMEA on what additional clinical data would be required. Even if approval from the EMEA might have been obtained more easily if Discovery had done the trial the EMEA proposed, that possibility is not sufficient to make statements as innocuous as "[t]he Company is also preparing an [MAA] to be filed with the [EMEA]," e.g. Compl. ¶ 79, false or misleading. That statement is factually correct and plaintiffs have not alleged such a lack of good faith that we can find it materially misleading.²⁵

²⁵ If Discovery had announced "we are certain that we have conducted sufficient clinical trials to obtain EMEA approval," this case might be different. Discovery made no such
(continued...)

Again, as with the Totowa statements, plaintiffs attempt to show materiality based on what happened when the information was finally revealed. And again they construct a misleading argument with post hoc reasoning. They contend that, because the stock dropped nineteen percent when Discovery Labs announced that it had withdrawn its MAA, the EMEA statements must have been material. That argument misses the mark. There is no question that withdrawal of the MAA was material. But there is also no allegation that Discovery withheld that information. Instead, we are asked to find that the subsequent drop in stock price proves that the disclosure that Discovery had adopted the FDA's required protocol over the EMEA's recommended one was material. Plaintiffs proffer no reason why we should make this link,²⁶ and we decline to do so.

For these reasons, we find that the EMEA standards statements are not materially misleading.

Scienter

The next requirement imposed on a Rule 10b-5 claim is that a plaintiff must allege that defendants acted with scienter. Under the PSLRA, for each alleged misstatement plaintiffs must

²⁵(...continued)
flat-footed statement.

²⁶ Indeed, the difference between the EMEA's proposed protocol and the one Discovery actually adopted was not even the stated reason for the withdrawal. As plaintiffs note in their complaint, quoting the relevant Form 8-K, "[t]he decision to withdraw is based on recently announced manufacturing issues that Discovery has now determined can not [sic] be resolved within the MAA review timetable." Compl. ¶ 177; Def. Br., Exh. 73.

"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). Plaintiffs may create that inference by "alleging facts 'establishing a motive and an opportunity to commit fraud, or by setting forth facts that constitute circumstantial evidence of either reckless or conscious behavior.'" In re Advanta Corp. Sec. Litig., 180 F.3d 525, 534-35 (3d Cir. 1999) (quoting Weiner v. Quaker Oats Co., 129 F.3d 310, 318 n.8 (3d Cir. 1997)). It is not enough, however, simply to allege that defendants stood to benefit from the alleged misstatements or had the opportunity to commit fraud. Advanta, 180 F.3d at 535. In addition, "[m]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud." GSC Partners CDO Fund v. Washington, 368 F.3d 228, 237 (3d Cir. 2004) (quoting Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001) (citation omitted)).

Plaintiffs' first attempt to show scienter is their claim that the VPFCs that Capetola and Schaber entered into in 2004 supported a strong inference of scienter. It is unclear how this could be. In essence, a VPFC is simply a sale of stock for which the seller is compensated immediately but is not required to deliver the shares for some time. They are called variable because if the stock price rises before the date of delivery, the seller is obligated to deliver fewer shares. Likewise, if the stock price falls before delivery, the seller must deliver more

shares. Thus, it was to Capetola and Schaber's advantage for the stock price to continue to rise during the contract period because then they would need fewer shares to deliver.

From a scienter standpoint, then, there is no real difference between the VPFCs here and any other sale of stock. Even if, as plaintiffs contend, Capetola and Schaber chose to use VPFCs rather than direct sales to avoid large sales by officers that might look bad immediately before a public offering, see Pl. Br. at 73-74, that reality would not affect our scienter analysis. The fact that the transactions' form was designed to be palatable to investors does not lead to a "strong inference" of fraudulent motives.

Our Court of Appeals has made it clear that it "will not infer fraudulent intent from the mere fact that some officers sold stock." Advanta, 180 F.3d at 540 (quoting Burlington Coat Factory, 114 F.3d at 1424). In order to support a legitimate inference of scienter, the sales must be "unusual in scope or timing." Id. Here, the sales were made well before the first sign of trouble and, although they are large, they are not big enough to support a finding of scienter under the heightened pleading standard of PSLRA.

Plaintiffs next try to find an inference of scienter by looking at Discovery's generation of equity financing agreements. They point out that in order to close the \$8 million in financing that Discovery managed to raise, defendants needed to keep the stock price high. This surely is the quintessential motive "generally possessed by most corporate directors and officers."

GSC Partners, 368 F.3d at 237. It does not show scienter. To say that Capetola and Schaber had a motive to keep the stock price high is tautological. Directors work for the shareholders, so they will always have a motivation to keep the stock price high. Indeed, that is why officers and directors are frequently given stock options or stock grants: it aligns their personal motivations with the shareholders'. That commonplace reality does not lead to a strong inference of scienter.

Finally, plaintiffs attempt to show scienter with regard to the Totowa statements and the EMEA standards statements under a recklessness theory. In 1979, our Court of Appeals adopted the Seventh Circuit's definition of recklessness in this context. A reckless statement is one that is "highly unreasonable" and 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." McLean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)²⁷ (quoting Sundstrand Corp. v. Sun Chemical Corp., 553 F.2d 1033, 1045 (7th Cir. 1977)). The Tenth Circuit applied the Seventh Circuit standard to a post-PSLRA case involving failure to disclose allegedly material facts in City of Philadelphia v. Fleming Cos., 264 F.3d 1245 (10th Cir. 2001). The Tenth Circuit

²⁷ Our Court of Appeals has cited McLean since the PSLRA was enacted. See SEC v. Infinity Group Co., 212 F.3d 180, 191-92 (3d Cir. 2000).

noted that "it is the danger of misleading buyers that must be actually known or so obvious that any reasonable man would be legally bound as knowing." Id. at 1260 (quoting Schlifke v. Seafirst Corp., 866 F.2d 935, 946 (7th Cir. 1989)). Under a recklessness theory, knowledge can be shown by demonstrating that the fact "was so obviously material that the defendant must have been aware both of its materiality and that its non-disclosure would likely mislead investors." Id. at 1261; Wilson v. Bernstock, 195 F. Supp. 2d 619, 639 (D.N.J. 2002).

In the preceding section we found that neither the Totowa statements nor the EMEA standards statements were material. Even if one were to disagree with that finding, the very fact that we were able to find the statements immaterial should demonstrate that they are not "so obviously material" as to allow a finding of recklessness under the standard in City of Philadelphia.

The PSLRA also makes clear that for forward-looking statements a recklessness theory cannot be used to show knowledge that the statement was false. 15 U.S.C. § 78u-5(c)(1)(B) requires that, for a forward-looking statement to be actionable, plaintiff must show "actual knowledge ... that the statement was false or misleading." Thus, for any forward-looking statement, a recklessness theory will not substitute for pleading actual knowledge on the part of the speaker. As we note below, most of the statements at issue here are forward-looking.

We hold, therefore, that plaintiffs have failed to adequately plead scienter as the PSLRA requires.

Optimism

It is well-settled that "vague and general statements of optimism 'constitute no more than "puffery" and are understood by reasonable investors as such.'" Advanta, 180 F.3d at 538 (quoting Burlington Coat Factory, 114 F.3d at 1428 n.14). Defendants contend in their brief that nearly half of the statements at issue in this case qualify as such "vague and general statements of optimism" and are therefore not actionable. See Def. Br. at 70-74. Defendants seem to ask us to find that the mere inclusion of a word such as "believe" or "might" is sufficient to create a general statement of optimism. We disagree. We find that only one of the challenged statements, statement 100, is the sort of general puffery that Advanta absolves. We therefore find that statement 100 cannot form the basis for plaintiffs' claim because it is mere puffery.

PSLRA Safe Harbor

The PSLRA creates a safe harbor for companies' forward-looking statements. Subject to exceptions not relevant here, the safe harbor protects companies from liability for any statement that is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i).

Before we examine the particular statements here, we must establish both what constitutes a forward-looking statement

and what will suffice for meaningful cautionary language. The statute defines a forward-looking statement, in relevant part,²⁸ as "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer," 15 U.S.C. § 78u-5(i)(1)(B), or "any statement of the assumptions underlying or relating to" such a statement, 15 U.S.C. § 78u-5(i)(1)(D). The Eleventh Circuit has placed a useful gloss on this language, noting that "a statement about the state of a company whose truth or falsity is discernible only after it is made necessarily refers only to future performance." Harris v. Ivax Corp., 182 F.3d 799, 805 (11th Cir. 1999). Thus, even a statement of present fact may become a forward-looking statement if a plaintiff's sole allegation of falsity is based on the existence of some future risk of failure. If a statement contains both present factual information and forward-looking information, we look at plaintiffs' allegation of the statement's falsehood and determine whether, in light of that allegation, the alleged falsity arises from the factual or the forward-looking aspects of the statement. If plaintiffs' allegation is rooted in the factual portion of the statement, the safe harbor will not protect it.

The required cautionary language must "relate directly to that by which plaintiffs claim to have been misled." Kline v.

²⁸ The definition of forward-looking statements is largely focused on financial predictions. Although those are frequently at issue in securities fraud cases, there is no allegation of misleading financial information in this case, so we need deal only with statements of corporate plans or objectives.

First W. Gov't Sec., Inc., 24 F.3d 480, 489 (3d Cir. 1994). The language must be "substantive and tailored" and cannot be mere boilerplate. In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 371 (3d Cir. 1993). The language need not be exhaustive. See Harris, 182 F.3d at 807. So long as the language meaningfully communicates to a potential investor the possibility that the predictions may not come to fruition and an understanding of what would cause this result, it suffices.

Each of the statements plaintiffs point to was accompanied by language mentioning both that some of the statements were forward-looking and that those predictions might not be realized due to certain risks. The list of likely risks changed over time and from one press release to another, undoubtedly in an attempt to make the cautionary language "substantive and tailored." This is not the sort of "vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks." Kline, 24 F.3d at 489 (quoting Trump, 7 F.3d at 371).

It is clear from the addition of the safe harbor provisions that Congress intended the PSLRA to allow companies to make forward-looking statements while insulating themselves from liability. If that intention is to be given any life at all, we must find as we do here that, where an allegedly false statement is forward-looking and where it is accompanied by relevant and meaningful cautionary language, defendants are insulated from liability based on the failure of the statement's expectations to come to pass.

Based on this analysis, we find that the PSLRA safe harbor covers statements 64, 65, 72, 79, 85, 86, 91, 92a, 92b, 97, 101, 103a, 103b, 118a, 120, 122, 123, 126, 127, 132, and 134. These statements cannot support plaintiffs' claims.

The 20(a) Claim

In addition to their Rule 10b-5 claims, plaintiffs also assert violations by controlling persons under Section 20(a) of the '34 Act, 15 U.S.C. § 78t(a). Because a claim for controlling person liability requires "proof of a separate underlying violation of the Exchange Act," Advanta, 180 F.3d at 541, and because we have found that no such underlying violation has been properly alleged, we will also dismiss plaintiffs' Section 20(a) claim.

Conclusion

For all but four of the allegedly false or misleading statements,²⁹ we have identified specific reasons why those statements cannot form the basis of a claim under Rule 10b-5. In addition, we have found that plaintiffs have failed to make the allegations of scienter that the PSLRA requires. Because the PSLRA's pleading requirements are high and otherwise worthy claims may occasionally get swept up in the broad net of securities reform, courts are generally inclined to liberally grant leave to amend a securities complaint. See Burlington Coat Factory, 114 F.3d at 1435. We see no reason to deny that

²⁹ The remaining statements are 67, 94, 104, and 135.

liberality here, and so offer one last bite at the apple.
Plaintiffs may, if they are able to further refine their claims
(particularly with regard to scienter), amend their complaint by
month's end.

BY THE COURT:

/s/ Stewart Dalzell, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: DISCOVERY LABORATORIES : MASTER FILE NO.
SECURITIES LITIGATION : 06-1820
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ORDER

AND NOW, this 1st day of November, 2006, upon consideration of defendants' motion to dismiss (docket entry # 43), plaintiffs' response (docket entry # 45), and defendants' reply (docket entry # 47) and for the reasons articulated in the accompanying Memorandum of Law, it is hereby ORDERED that:

1. Defendants' motion to dismiss is GRANTED;
2. Plaintiffs' consolidated amended complaint is DISMISSED; and
3. Plaintiffs may FILE a consolidated second amended complaint by November 30, 2006.

BY THE COURT:

/s/ Stewart Dalzell, J.