KeyCite Yellow Flag - Negative Treatment
Distinguished by Lin v. Interactive Brokers Group, Inc., S.D.N.Y., August 22, 2008

279 F.Supp.2d 171
United States District Court,
S.D. New York.

In re ALLIANCE PHARMACEUTICAL CORP. SECURITIES LITIGATION

No. 01 Civ.1674 CM.
|
Aug. 13, 2003.

Synopsis
Shareholders of acquired corporation sued acquiring corporation and its principals, alleging registration statement and prospectus misrepresentation in violation of Securities Act. Defendants moved for summary judgment. The District Court, McMahon, J., held that: (1) acquiring corporation had no duty to disclose adverse development regarding testing of its drug product, as of date of registration statement, precluding claim of registration statement misrepresentation liability; (2) fact issue as to materiality of nondisclosure precluded summary judgment of nonliability for prospectus misrepresentation; (3) statement that capital was adequate was not registration statement or prospectus misrepresentation; (4) fact issues precluded summary judgment that statements regarding licensing of acquired corporation's product were registration statement or prospectus misrepresentation; and (5) survival of some underlying claims precluded summary judgment of no control person liability under Securities Act.

Motion granted in part, denied in part.

West Headnotes (14)

[1] **Securities Regulation** False Statements or Omissions; Accuracy

Securities Act does not require a corporation to disclose a fact merely because a reasonable investor would like very much to know that fact; rather, an omission is actionable only when the corporation is subject to a duty to disclose the omitted facts. Securities Act of 1933, §§ 11, 12(a)(2), as amended, 15 U.S.C.A. §§ 77k, 77*l*(a)(2).

5 Cases that cite this headnote

[2] **Securities Regulation** False Statements or Omissions; Accuracy

Securities Regulation False Statements or Omissions; Accuracy

Threshold requirement for a registration statement or prospectus misrepresentation claim, under Securities Act, based on failure to disclose information, is presence of affirmative statement that is made misleading by material omission. Securities Act of 1933, §§ 11, 12(a)(2), as amended, 15 U.S.C.A. §§ 77k, 77*l*(a)(2).

4 Cases that cite this headnote

[3] **Securities Regulation** Materiality; Reliance

Securities Regulation Materiality

Undisclosed information is "material," for purposes of registration statement or prospectus misrepresentation under Securities Act, if there is substantial likelihood that disclosure would have been viewed by reasonable investor as having significantly altered the total mix of information made available. Securities Act of 1933, §§ 11, 12(a)(2), as amended, 15 U.S.C.A. §§ 77k, 77*l*(a)(2).

3 Cases that cite this headnote

[4] **Securities Regulation** False Statements or Omissions; Accuracy

Date for determining whether registration statement covering merger contained any untrue statements of material facts, or omitted material facts needed to make stated facts not misleading, was date registration statement became effective. Securities Act of 1933, § 11, as amended, 15 U.S.C.A. § 77k.

1 Cases that cite this headnote

[5] **Securities Regulation** Materiality

Time of purchase of securities is the crucial moment for the determination of materiality of statements or omissions, for purposes of prospectuses misrepresentation claims under Securities Act. Securities Act of 1933, § 12(a)(2), as amended, 15 U.S.C.A. § 77*l*(a)(2).

1 Cases that cite this headnote

[6] **Securities Regulation** Particular Prospectuses or Communications

Time for determining whether prospectus issued by acquiring company in merger contained material misrepresentations, or omitted facts required to render representations not misleading, in violation of prospectus misrepresentation provision of Securities Act, was date when parties became legally committed to each other as result of acquiring corporation's purchase of acquired corporation's shares, which occurred during five day period between merger approval vote by acquired corporation's board of directors and date merger was announced. Securities Act of 1933, § 12(a)(2), as amended, 15 U.S.C.A. § 77*l*(a)(2).

2 Cases that cite this headnote

[7] **Securities Regulation** False Statements or Omissions; Accuracy

On date that registration statement became effective, corporation producing oxygen carrying agent, used as substitute for blood during surgery, had no duty, under registration statement misrepresentation provision of Securities Act, to modify statement that early test results from European test showed that product significantly reduced need for donor blood, to reflect problems surfacing in United States study; as of that date only potentially adverse information was higher incident of adverse neurological reactions in test group than control group, which was statistically insignificant, and findings had been reported to independent board, which allowed continuation of study. Securities Act of 1933, § 11, as amended, 15 U.S.C.A. § 77k.

4 Cases that cite this headnote

[8] **Federal Civil Procedure** Securities Cases in General

Material issues of fact, as to whether corporation issued prospectus containing material omission by not stating that patient test group being given oxygen carrier as substitute for blood during surgery would undergo change in composition, to exclude patients with certain neurological predispositions, precluded summary judgment whether there was prospectus misrepresentation in violation of Securities Act. Securities Act of 1933, § 12(a)(2), as amended, 15 U.S.C.A. § 77*l*(a)(2).

[9] **Securities Regulation** False Statements or Omissions; Accuracy

Neither the bespeaks caution doctrine nor the Safe Harbor provision of the PSLRA, providing securities liability protection for forward looking statements accompanied by adequate cautionary language, protects a defendant from liability if a statement was knowingly false when made. Securities Act of 1933, § 27A(c), as amended, 15 U.S.C.A. § 77z–2(c). .

9 Cases that cite this headnote

[10] **Securities Regulation** False Statements or Omissions; Accuracy

Securities Regulation Particular Prospectuses or Communications

Corporation producing oxygen carrier, for use as blood substitute during surgery, did not make knowingly false statement in registration statement or prospectus, by declaring that its capital resources will satisfy capital requirements through fiscal year; fact that standards for determining appropriate patients for United States testing of carrier were being changed, at time statement was being made, did not mandate conclusion that capital resources would be inadequate. Securities Act of 1933, §§ 11, 12(a)(2), as amended 15 U.S.C.A. §§ 77k, 77*l*(a)(2).

2 Cases that cite this headnote

[11] **Securities Regulation** Particular Prospectuses or Communications

Statement required to be included in merger agreement, that related prospectus will not contain untrue statement of material fact or omit statement required to make others not misleading, did not provide additional cause of action to shareholders of acquired corporation, over and above that provided in Securities Act. Securities Act of 1933, § 1 et seq., as amended, 15 U.S.C.A. § 77a et seq.

[12] **Securities Regulation** Materiality; Reliance

Securities Regulation Materiality

Event need not be finalized, in order to be material for disclosure purposes, under registration statement and prospectus misrepresentation provisions of Securities Act. Securities Act of 1933, §§ 11, 12(a)(2), as amended, 15 U.S.C.A. §§ 77k, 77*l*(a)(2).

1 Cases that cite this headnote

[13] **Securities Regulation** Particular Prospectuses or Communications

Material issues of fact, as to whether failure of prospectus issued by acquiring corporation in connection with merger to refer to acquired corporation's license agreement with patent infringement claimant made prospectus statements regarding difficulties of marketing acquired corporation's product in Asia unduly gloomy, precluded claim of prospectus misrepresentation in violation of Securities Act. Securities Act of 1933, § 12(a)(2), as amended, 15 U.S.C.A. § 77*l*(a)(2).

[14] **Federal Civil Procedure** Securities Cases in General

Survival of claims that there were two instances of prospectus misrepresentations or omissions, in violation of Securities Act, precluded summary judgment of no control person liability on part of principals of issuing corporation. Securities Act of 1933, §§ 12(a)(2), 15,as amended, 15 U.S.C.A. §§ 77*l*(a)(2), 77*o*. .

1 Cases that cite this headnote

Attorneys and Law Firms

***173** Joel C. Feffer, Wechsler, Harwood LLP, New York, NY, for Plaintiffs.

Alan M. Klinger, James L. Bernard, James L. Bernard, Stroock & Stroock & Lavan, L.L.P., New York, NY, Julia Beatrice Strickland, Mary Deanna Manesis, Stroock & Stroock & Lavan LLP, Los Angeles, CA, for Defendants.

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

MCMAHON, District Judge:

Plaintiffs, former shareholders of Molecular Biosystems, Inc. ("MBI"), bring this action against Alliance Pharmaceutical Corp. ("Alliance") and three of its officers—Duane J. Roth ("D. Roth), Theodore D. Roth ("T. Roth"), and Tim T. Hart ("Hart")—under Sections 11 and 12(a)(2) of the Securities Act of 1933 (15 U.S.C. §§ 77k, 77*l*). Plaintiffs also allege that the individual defendants, as control persons of Alliance, violated Section 15 of the Securities Act of 1933 (15 U.S.C. § 77*o*). Defendants move for summary judgment under Fed.R.Civ.P. 56 on all of the plaintiffs' claims.

Defendants' motion is granted in part and denied in part.

***174 I. BACKGROUND**

A. Factual History

The following facts, unless otherwise noted, are undisputed.

1. *The Merger of Alliance and MBI and the Commencement of this Lawsuit*

Defendant Alliance, a New York corporation, is a pharmaceutical research and development company.

(Defendants' 56.1 Statement ("Def. 56.1"), 6.) Alliance is the developer of Oxygent, a temporary oxygen carrier or blood substitute designed to reduce or eliminate the need for blood transfusions during surgery. *Id.* at 7. MBI is the developer of Optison, an intravenous ultrasound contrast agent used in ultrasound examinations of the heart. *Id.* at 94.

In October 2000, Alliance and MBI announced that they had entered into an agreement for Alliance to acquire MBI. *Id.* at 1. Under the terms of the parties' merger agreement, Alliance would acquire all of MBI's stock in exchange for 770,000 shares of Alliance stock and MBI would become a wholly-owned subsidiary of Alliance. *Id.* at 2. In connection with the proposed merger and stock exchange, Alliance filed a Registration Statement with the Securities and Exchange Commission on November 9, 2000 and two amendments thereto on November 22 and 29, 2000 (collectively the "Registration Statement"). *Id.* at 3. The Registration Statement included a proxy statement-prospectus. The Registration Statement was declared effective by the SEC on November 29, 2000. *Id.* at 4.

On December 29, 2000, at a special shareholder's meeting, the shareholders of MBI voted to approve the merger. *Id.* at 5. [1] On January 3, 2001, Alliance issued a press release announcing that it had completed its acquisition of MBI. (SAC, 9.)

On January 8, 2001, Alliance issued a press release publicly disclosing that it had voluntarily suspended further patient enrollment in its Phase 3 study of Oxygent in cardiac surgery patients due to an imbalance in certain adverse events between the control group and the Oxygent treatment group. (Def. 56.1, 82.)

Plaintiffs allege that this announcement had a devastating effect on the stock prices of both companies. On the day preceding the merger announcement, MBI common stock closed at $0.45 per share, while Alliance common stock closed at $13.50 per share. (SAC, 2.) On January 3, the day the merger was announced, Alliance's common stock traded as high as $8.813 per share and closed at $8.625 per share. *Id.* at 9. On January 8, when Alliance announced the suspension of the Oxygent trial, the price of Alliance common stock plunged 62% from the previous day's closing price of $7.50, to close at $2.375 per share. *Id.* at 11. Plaintiffs allege that on ***175** January 22, 2001, Alliance issued a report stating that (1) it would reduce its workforce by approximately 20%; and (2) the bulk of the staff positions eliminated were those "involved in preparations for the anticipated near-term commercialization of Oxygent." *Id.* at 14. Plaintiffs also allege that "[i]t was reported that contrary to the representations in the Registration Statement, the Company may not have sufficient cash to meets [sic] its working capital commitments for the current fiscal year." *Id.* at 14. [2]

On February 23, 2001, in response to the precipitous drop in the value of their stock, plaintiffs filed this action on behalf of all individuals—except defendants and related parties—who acquired common stock of Alliance pursuant to the merger between MBI and Alliance. Plaintiffs filed their second amended complaint on February 14, 2002. Plaintiffs allege that defendants failed to disclose (1) known problems in the Phase 3 study of Oxygent, (thereby inflating Alliance's value), and (2) information about an agreement between MBI and "its only viable competitor" for Optison sales in Japan, South Korea, and Taiwan (thereby deflating MBI's value). (SAC 4, 7, 8.)

2. *The Clinical Testing of Oxygent*

At the time that the Registration Statement became effective, on November 29, 2000, Alliance had three main products under development. *Id.* at 6. One of those products—characterized by plaintiffs as Alliance's "premiere" product—was Oxygent, an intravenous temporary oxygen carrier that was being developed to reduce or eliminate the need for blood transfusions during surgery. *Id.* at 7. As of November 29, Oxygent was being evaluated in two "Phase 3" clinical trials. *Id.* at 13. Phase 3 trials, which are trials in patients, are the final stage of trials required prior to requesting marketing approval from regulatory agencies. *Id.* at 13, 18. Oxygent had also been previously evaluated with human subjects in eighteen other clinical trials. *Id.* at 14.

One of the Phase 3 studies was being conducted in Europe on patients undergoing general surgery. (SAC, 44.) In September, 2000, Alliance announced that the initial results of the European study showed that Oxygent provided a statistically significant reduction in the need for donor blood. *Id.* at 45. The other Phase 3 study, which began in December 1999, was being conducted in the United States. (Def. 56.1, 16, 17.) The subjects of that trial were undergoing cardiac bypass surgery. *Id.* It is the progress of the United States cardiac trial that is at issue in this case.

Alliance established a Data Safety Monitoring Board ("DSMB") to monitor patient safety during the Phase 3 cardiac trial. *Id.* at 19. The DSMB was an independent committee of five experts: four physicians, all of whom had expertise and extensive experience in cardiac surgery and anesthesiology, and a biostatistician. *Id.* at 21. The DSMB was responsible for periodically reviewing safety data from the Oxygent cardiac trial as it progressed to ensure patient safety and maintain the integrity of the trial. *Id.* at 22. The DSMB had no involvement in the conduct of the cardiac trial, and its review of safety data was independent from Alliance and the principal investigators conducting the trial. *Id.* at 23. The DSMB was authorized to make ***176** recommendations to Alliance regarding modification or termination of the cardiac trial based on its interim reviews of safety data. *Id.* at 24. The DSMB met quarterly to discuss its interim review of accruing safety data from the Oxygent cardiac trial. *Id.* at 25. Certain Alliance clinical and medical personnel were invited to participate in open sessions of the DSMB meetings. *Id.* at 26. At the closed DSMB meetings, which were attended only by DSMB members, the DSMB reviewed unblinded safety data and discussed trial results and trends and any recommendations regarding the trial. *Id.* at 27.

At the outset of the cardiac trial, the DSMB and Alliance agreed to specially track neurological post-operative complications, since they are a known risk of bypass surgery, particularly in older patients and patients with a history of cerebrovascular disease. *Id.* at 33. On October 18, 2000, the DSMB held its third meeting with Alliance personnel to review safety data from more than 200 patients in the Oxygent cardiac trial. *Id.* at 34. In reviewing safety data for the October 18 meeting, the DSMB observed that adverse neurological events appeared to be more prevalent in the treatment group receiving Oxygent than the control group not receiving Oxygent, particularly in patients who were 70 years or older. *Id.* at 35. However, the difference in the incidence of adverse neurological events between the two groups was not statistically significant. *Id.* at 36. DSMB performed further statistical analyses, and indicated that the issue of adverse neurological events would be reviewed at the next DSMB meeting scheduled for January 31, 2001. *Id.* at 37. Alliance agreed to contact the DSMB upon receiving new reports of stroke in the trial. *Id.* at 38. The DSMB concluded the October 18, 2000 meeting by recommending that the trial proceed uninterrupted and additional patients be recruited. *Id.* at 39.

On December 19 and 20, 2000, Dr. Hans de Haan, acting director of Alliance's Product Safety Surveillance Department ("PSSD"), learned that two additional patients in the Oxygent cardiac trial group had suffered strokes. *Id.* at 10, 40. These two additional strokes rendered the difference in incidence in adverse neurologic events between the treatment group and control group statistically significant for the first time. *Id.* at 41. However, the stroke incidence in the Oxygent group was consistent with the expected stroke incidence for cardiac bypass patients published in medical literature, while the stroke incident in the control group was "below the expected incidence and remarkably low." *Id.* at 42, 43.

Consistent with Alliance's guidelines regarding the trial protocol, a meeting was held on December 21, 2000 so that Dr. de Haan could apprise his superiors, Dr. Joerg Limmer and Dr. Howard Dittrich, about the new strokes and the statistically-significant difference in stroke incidence between the treatment and control groups. *Id.* at 45. Dr. Limmer was Alliance's Vice President of World–Wide Clinical Development. Dr. Dittrich was an MBI officer who was a clinical consultant to Alliance and was scheduled to become its Chief Medical Officer after the merger with MBI. *Id.* at 44. According to plaintiffs, Dr. Dittrich was also Vice President of Regulatory Affairs at Alliance. (Pltf.Resp., 44.) Steve Balyakin, a PSSD member, also attended the meeting. (Def. 56.1, 44.)

As reflected in Dr. de Haan's minutes of the meeting, the meeting participants discussed the fact that no patients had died as a result of stroke, none of the strokes was considered to be directly related to Oxygent by the trial investigators, and no similar stroke finding had been observed ***177** in the many prior clinical trials of Oxygent. *Id.* at 46. After reviewing safety data from the trial, Dr. de Haan, Dr. Limmer, and Dr. Dittrich concluded that older patents and patients with a history of strokes appeared to be at higher risk of stroke than other patients in the trial. *Id.* at 48. Their conclusion was consistent with medical literature on stroke incidence in cardiac bypass patients. *Id.* at 50. Dr. de Haan, Dr. Limmer, and Dr. Dittrich decided to advise the DSMB of the stroke finding, draft a proposal excluding older patients with a history of strokes from the trial, and distribute a notice to trial investigators informing them of the new exclusion criteria. *Id.* at 51.

Accordingly, on the day following the meeting—December 22, 2000—Dr. de Haan called Dr. John Murkin, a DSMB member who is an expert in strokes after bypass surgery. *Id.* at 53, 54. Dr. de Haan and Dr. Murkin agreed that the exclusion criteria for the trial should be changed to exclude patients who

were 70 years old or older or had a history of cerebrovascular disorders, including strokes, or were at increased risk of such disorders. *Id.* at 53, 54. Later that day, Dr. de Haan sent an e-mail to Dr. Andrew Wechsler, the DSMB chairperson, notifying him of the stroke finding and of his conversation with Dr. Murkin. *Id.* at 57. Dr. de Haan also provided Dr. Wechsler with a draft letter to the trial sites. *Id.* at 57.

On December 26, 2000, Dr. Weschsler spoke with Dr. de Haan and endorsed Alliance's plan to change the trial exclusion criteria and notify the trial sites. *Id.* at 59. Dr. de Haan then notified the trial sites of the stroke finding and the new exclusion criteria. *Id.* Alliance began preparations to notify the FDA of the change in exclusion criteria and to amend the trial protocol. *Id.* at 60. Duane Roth, Alliance's CEO, and Ted Roth, Alliance's President, were also apprised of the neurological imbalance between the trial groups, as well as the recommendation reached by Alliance medical personnel and the DSMB that the trial proceed with new exclusion criteria. *Id.* at 61.

On December 29, 2000, Dr. de Haan and several other Alliance clinical and medical personnel spoke by telephone with Dr. Murkin. *Id.* at 62. Dr. Murkin agreed that the steps taken by Alliance were timely, appropriate, and reasonable. *Id.* at 63. However, Dr. de Haan expressed a desire to better understand why patients in the Oxygent group appeared more likely to experience strokes. *Id.* at 64. Accordingly, during Alliance's conversation with Dr. Murkin, the parties discussed possible explanations for the increased stroke incidence in the Oxygent group, including specific trial procedures used exclusively in that group. *Id.* at 65. Dr. Murkin recommended that Alliance review a published preoperative stroke risk index for cardiac bypass patients, which, although not yet validated, might serve as a guide in predicting which patients were at increased risk of stroke and should be excluded from trial. *Id.* at 66.

Within a day of the December 29, 2000 conversation, Dr. de Haan obtained the stroke risk index recommended by Dr. Murkin. *Id.* at 67. Dr. de Haan and the DSMB statistician then developed a statistical modeling approach for using the stroke risk index and the safety data from the cardiac trial in order to predict which patients in the trial were at a greater risk of stroke. *Id.* at 68.

To this point in the chronology of events, plaintiffs admit, without qualification, that defendants' version of the facts regarding Oxygent is correct.

According to Defendants' Rule 56.1 statement, on January 4 or 5, 2001, Dr. de ***178** Haan received several graphs from the DSMB statistician reflecting the results of the statistical modeling. *Id.* at 69. The graphs showed that all patients in the Oxygent group of the cardiac trial, regardless of age, were at increased risk of a stroke. *Id.* at 70. In addition, on or about January 4, 2001, Dr. de Haan determined that there were imbalances between the Oxygent and control groups with respect to post-operative bleeding complications. *Id.* at 72. Dr. de Haan approached his superiors, Dr. Limmer and Dr. Dittrich, on Friday, January 5, 2001 to discuss the results of the neurological statistical modeling and the bleeding imbalances. *Id.* at 73. Plaintiffs do not offer any evidence which disputes this version of events.

Plaintiffs admit, without qualification, only that on January 4, 2001, Dr. de Haan determined that there were post-operative bleeding imbalances between the control and the study groups. As to all other facts relating to the period between January 1 to 5, 2001, plaintiffs state only that they are admitted "to the extent supported by Dr. de Haan's testimony" and the relevant exhibits." (Pltf.Resp., 69–73.) Dr. de Haan's testimony and the related exhibits support all of defendants' factual assertions and, significantly, plaintiffs provide no evidence to controvert any of them. I therefore accept them as true and undisputed for purposes of this motion.

Both parties agree that on Monday, January 8, 2001, Alliance held a meeting at which Dr. de Haan presented the results of the neurological statistical modeling and recommended that the trial be suspended based on the new findings. *Id.* at 78. That day, Dr. de Haan informed Dr. Wechsler of Alliance's decision to suspend patient enrollment until the new trial data could be better understood. (Def.56.1, 80.) Alliance immediately notified the FDA and the trial sites that the trial was being suspended. *Id.* at 81.

Also on January 8, Alliance issued the press release discussed above, announcing that it had voluntarily suspended enrollment in the Oxygent cardiac trial due to an imbalance in certain adverse events, primarily the incidence of stroke, between the Oxygent group and the control group. *Id.* at 82. Alliance also stated that the trial investigators had not attributed the adverse events to Oxygent. *Id.* at 84. The stock price dropped precipitously. (SAC, 11.)

A year later, in January 2002, Alliance announced that a comprehensive safety analysis, using data from the cardiac

trial and all other Oxygent clinical trials, concluded that the stroke imbalance in the cardiac trial resulted from differences in trial procedures and was not directly related to Oxygent. (Def.56.1, 91–92.) At the time Defendants filed their 56.1 Statement, they claimed Alliance was "currently" engaged in discussions with the FDA concerning the Oxygent safety analysis and new clinical plan, and had received approval to conduct a Phase 3 trial of Oxygent in Europe with modified trial procedures. *Id.* at 93. Plaintiffs admit only "that it is an accurate description" of exhibits submitted by defendants—PR Newswires announcing same. (Pltf. 56.1, 93.) But, again, plaintiffs do not introduce any evidence that contradicts the facts as asserted by defendants. [3]

3. *The Optison Agreement*

As previously noted, MBI is the developer of Optison, an intravenous ultrasound ***179** contrast agent used in ultrasound examinations of the heart. *Id.* at 94. Prior to the merger, MBI had entered into collaborative agreements with Mallinckrodt, Inc. and Chugai Pharmaceutical Co. Ltd., pursuant to which the two companies assumed all development, manufacturing, and marketing responsibilities for Optison in their respective territories. *Id.* at 96–100.

Mallinckrodt controlled the Optison business for all territories except Japan, South Korea, and Taiwan. *Id.* at 97. At the time that the Registration Statement became effective, Optison had received regulatory approval and was being marketed by Mallinckrodt in the United States and Europe. *Id.* at 95, 97. MBI was entitled to royalties on Mallinckrodt's sales of Optison. *Id.* at 98.

Chugai had a right to distribute Optison in Japan, South Korea, and Taiwan. *Id.* at 99. At the time that the Registration Statement became effective, Chugai was conducting Phase 3 clinical trials of Optison in Japan. *Id.* at 95. MBI was entitled to "milestone payments" from Chugai, based on Chugai's achievement of certain product development and regulatory goals, and royalties from Chugai on any future sales of Optison in its territories. *Id.* at 100.

In May 2000, MBI and Mallinckrodt settled litigation brought by two of MBI's competitors (Sonus and Nycomed Amersham plc), who had alleged that Optison sales by MBI in the United States and Europe infringed their patents. *Id.* at 102. Pursuant to the settlement, Sonus became entitled to royalties on sales of Optison by MBI and Mallinckrodt, with the exception of sales in certain Asian countries, including Chugai's territories. *Id.* at 103.

On January 16, 2001, Sonus announced that it had entered into a patent licensing agreement with Chugai and MBI with respect to the development and marketing of Optison in Chugai's territories (referred to by the parties as the "Sonus License Agreement"). *Id.* at 104. Pursuant to the Sonus License Agreement, Chugai and MBI received non-exclusive rights under certain Sonus patent applications and patents to develop, manufacture, and sell Optison in Chugai's territories. *Id.* at 105. In addition, Chugai agreed to pay Sonus an initial $1 million license fee after the signing of the agreement and a second $1 million license fee (refundable under certain circumstances not relevant here) in June 2001. *Id.* at 106, 107. Chugai and MBI also agreed to pay royalties to Sonus on sales of Optison if and when it was approved for marketing in the Chugai territories. *Id.* at 108. The Sonus License Agreement granted Chugai and MBI license rights under patent applications that Sonus had pending, rather than patents that had issued to Sonus; there was no guarantee that the applications would be granted. *Id.* at 136.

Plaintiffs allege that the Sonus License Agreement was reached well before it was announced on January 16, 2001. (Plaintiffs' Memorandum in Opposition to Summary Judgment, p. 14.) Plaintiffs point to a September 13, 2000 letter from Bobba Venkatadri, President and CEO of MBI, to Ted Roth, President and COO of Alliance, informing him that MBI had "reached a handshake agreement for the terms of licensing Sonus patents in Chugai territory." *Id.* (citing Ex. 8 to the Declaration of Joel C. Feffer). Plaintiffs also note that the licensing agreement itself is dated "as of December 22, 2000." *Id.* (citing Ex. A to the Declaration of Howard C. Dittrich, M.D.).

Nevertheless, both plaintiffs and defendants admit that, as late as December 27 or 28, 2000, there were serious disagreements between the parties to the Sonus license agreement over the terms of the ***180** contract. It is undisputed that the possibility of reaching an agreement was threatened when Sonus refused to agree to a covenant not to sue proposed by Chugai; on December 27, 2000, at 10:02 p.m., Michael Martino of Sonus sent an e-mail to Joseph M. Connell, Executive Director of Marketing and Business Development at MBI that attached a "redlined" version of the draft agreement, with Chugai's comments, and that stated: "Given this apparent impasse over an asinine issue and Alliance's last minute comments, I have informed my Board that it is

unlikely that this deal will be consummated. Frankly, my strategy is to enjoy the rest of the holiday with my family and reevaluate Sonus' options in the light of the new year." (Def. 56.1, 116; Ex. D to the Declaration of Joseph M. Connell, Jr.)

Despite Martino's email, the parties continued negotiations until at least December 28, 2000. (Def.56.1, 119.) The covenant not to sue was revised as demanded by Sonus and, on December 29, 2000, Chugai faxed Sonus copies of the Sonus License agreement, signed by Chugai. *Id.* at 120, 121. Chugai requested that Sonus sign the agreement and send it to MBI for its signature; Sonus did so the same day. *Id.* at 120, 122.

When Sonus sent the signed agreement to MBI, it stated that it was aware, based on prior discussions, that Alliance had requested language in the agreement giving MBI the right to sublicense the Sonus patents in the event the licensing agreement between Chugai and MBI terminated. *Id.* at 123. Sonus proposed that Sonus and MBI handle the issue in a side letter. *Id.* at 124. MBI then signed a faxed copy of the Sonus License Agreement on December 29, 2000, but conditioned its delivery of the agreement on reaching a side agreement with Sonus. *Id.* at 125. MBI also faxed a letter containing the terms of this side agreement and stating that the agreement was not to be considered delivered unless Sonus countersigned the side letter and returned it to MBI. *Id.* at 125, 126.

On January 2, 2001, Sonus returned the letter, signed, with an added term. *Id.* at 128. Sonus requested that MBI initial the added term and return the letter to Sonus, or revise the letter to reflect the change and send it back to Sonus to be signed again. *Id.* at 129. MBI agreed to the additional term and initialed the proposed change to the letter. *Id.* at 130. Both parties concede that it is not clear from the record exactly when MBI initialed and agreed to the change, but they agree that it must have been some time between January 2, 2001 and January 16, 2001, when Sonus issued a press release announcing that it had entered into the Sonus License Agreement with Chugai and MBI. *Id.* at 132.

B. Procedural History

Plaintiffs brought their original complaint on February 23, 2001. On May 22, 2001, the Honorable Charles L. Brieant ordered this action consolidated with two civil actions that had already commenced, both of which also brought claims under the Securities Act of 1933 based on allegedly misleading statements regarding Oxygent. Judge Brieant appointed the plaintiffs as lead plaintiffs of the consolidated action and appointed Wechsler Harwood LLP as lead plaintiffs' counsel. On behalf of the class, lead counsel filed a consolidated amended complaint on July 9, 2001.

On August 13, 2001, defendants moved under Fed.R.Civ.P. 12(b)(6) to dismiss plaintiffs' consolidated amended complaint. On October 5, 2001, defendants filed an opposition to the motion to dismiss and moved for leave to file a second consolidated amended complaint—seeking to add a ***181** claim under Section 12(a)(2) of the Securities Act of 1933.

The action was reassigned from Judge Brieant to me, and on January 14, 2002, I denied defendants' motion to dismiss, without prejudice to renew their arguments in a motion for summary judgment. I also granted plaintiffs' motion for leave to file a second amended complaint. Plaintiffs did so on February 14, 2002. With the consent of the parties, I granted a motion to certify the complaint as a class action on March 13, 2002. After discovery, defendants moved for summary judgment under Fed.R.Civ.P. 56.

II. DISCUSSION

A. Summary Judgment Standard

A party is entitled to summary judgment when there is no "genuine issue of material fact" and the undisputed facts warrant judgment for the moving party as a matter of law. Fed.R.Civ.P. 56(c), *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). When considering a motion for summary judgment, "the court must view the evidence in the light most favorable to the party against whom summary judgment is sought and must draw all reasonable inferences in [its] favor." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. *Celotex v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once the moving party has made such a showing, the non-moving party must present "specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The party opposing summary judgment "may not rely on conclusory allegations or unsubstantiated speculation." *Scotto v. Almenas,* 143 F.3d 105, 114 (2d Cir.1998). Moreover, not every disputed factual issue is material in light of the

substantive law that governs the case. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude summary judgment." *Anderson,* 477 U.S. at 248, 106 S.Ct. 2505.

B. Federal Securities Claims

Plaintiffs bring claims under 15 U.S.C. §§ 77k and 77*l* (a)(2) ("Section 11" and "Section 12(a)(2)" respectively), alleging that the Registration Statement and Prospectus omitted material facts that were necessary to make particular statements therein not misleading. *See* 15 U.S.C. § 77k; 15 U.S.C. § 77*l.* Plaintiffs also bring a claim against the individual defendants for violation of 15 U.S.C. § 77*o* ("Section 15"), which provides that "every person who ... controls any person liable under sections 77k or 77*l* of this title, shall also be liable jointly and severally with and to the same extent as such controlled person...." As a remedy for each claim, plaintiffs seek rescission of their stock purchases to the extent that they continue to own such securities.

Section 11 imposes liability on certain enumerated individuals, including all signers of a registration statement and every underwriter with respect to such security, if "when such part [of the Registration Statement] became effective, [it] contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading...." 15 U.S.C. § 77k(a). The registration statement was signed by each of the individual defendants—D. Roth, Chairman of Alliance's Board of Directors and its Chief Executive Officer; T. Roth, Executive Vice President and Chief Financial Officer; and Hart, Treasurer, Chief Financial Officer, ***182** Chief Accounting Officer and Vice President of the Company. Plaintiffs allege that defendant Alliance is liable under Section 11 because it acted as the underwriter by issuing and disseminating its own shares. (SAC, 87.) Defendants do not dispute that Alliance is subject to liability under Section 11 for its role in the transaction.

Section 12(a)(2) imposes liability on "any person who offers or sells a security ... by means of a prospectus or oral communication, which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading...." Again, plaintiffs bring the claim against all defendants, and defendants do not dispute that they may be subject to liability under Section 12 for their respective roles in the transaction.

Plaintiffs' Section 15 claim, against the individual defendants, are predicated on the alleged Section 11 and Section 12 violations. Because there can be no individual liability under Section 15 without an underlying violation of Section 11 or 12, I consider the Section 11 and Section 12 claims first.

[1] Sections 11 and 12(a)(2) are enforcement mechanisms for the mandatory disclosure requirements of the Securities Act of 1933. *Freedman v. Value Health, Inc.,* 135 F.Supp.2d 317, 330 (D.Conn.2001). The securities laws do not require a corporation "to disclose a fact merely because a reasonable investor would like very much to know that fact. Rather, an omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts." *In re Time Warner, Inc., Sec. Litig.,* 9 F.3d 259, 267 (2d Cir.1993) (citations omitted). A duty to disclose specific information may arise from express mandates of the federal securities laws, and the rules promulgated under them, or in the general anti-fraud provisions of the statutes and rules. *L.L. Capital Partners v. Rockefeller Center Properties, Inc.,* 921 F.Supp. 1174, 1179 (S.D.N.Y.1996).

[2] **[3]** Plaintiffs allege both that certain statements were false when they were made and that the statements were misleading because defendants failed to disclose other facts. A threshold requirement for a Section 11 and Section 12(a)(2) claim based on a failure to disclose information is the presence of an affirmative statement that is made misleading by the material omission. *In re Union Carbide Class Action Sec. Litig.,* 648 F.Supp. 1322, 1326 (S.D.N.Y.1986). A defendant is not required to disclose all known information, but has a duty to disclose any information that is "necessary to make other statements not misleading." *In Re Donald J. Trump Casino Sec. Litig.,* 7 F.3d 357, 369 n. 13 (3d Cir.1993). In such a case, "where the disclosure duty arises from the combination of a prior statement and a subsequent event, which, if not disclosed, renders the prior statement false or misleading, the inquiries as to duty and materiality coalesce." *In re Time Warner Sec. Litig.,* 9 F.3d at 259. "The undisclosed information is material if there is 'a substantial likelihood that the disclosure [ ] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.' " *Id.* (quoting *TSC Industries, Inc. v. Northway Inc.,* 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976)); *see also Kronfeld v. Trans World Airlines, Inc.,* 832 F.2d 726, 731 (2d Cir.1987).

Plaintiffs claim that defendants made four statements that were false or misleading due to material omissions. *See*

II. D., *infra.* Before considering the materiality of the alleged omissions, I must determine the appropriate dates for determining materiality under Section 11 and Section ***183** 12(a)(2). The relevant dates are crucial in this case, because information regarding both Oxygent and the Sonus agreement was developing during the same time period that Alliance and MBI were undergoing the merger.

C. The Relevant Dates for Determining Materiality Under Section 11 and Section 12(a)(2)

Defendants argue that plaintiffs may only recover under Section 11 and Section 12(a)(2) if an omission of a material fact made the registration statement and prospectus misleading as of the date that the registration statement became effective—in this case, November 29, 2000. (Defendants' Memorandum in Support of Summary Judgment ("Def. Mem."), 19.) Plaintiffs claim that the registration statement and prospectus contained misleading material omissions as of November 29. (Plaintiffs' Memorandum in Opposition to Summary Judgment, ("Pltf. Mem."), 14.) But they also argue that Alliance had an affirmative duty to amend both the registration statement and the prospectus to reflect the occurrence of events subsequent to the effective date. (Pltf. Mem., 20.) Plaintiffs assert that, for purposes of Section 12(a)(2) liability, the operative date is December 29, 2000—the date that the MBI shareholders voted on the merger with Alliance. *Id.* at 3. Plaintiffs also maintain that December 29, 2000 should be the operative date for purposes of Section 11 liability, but qualify their argument by stating that "it is, at best, an open question in the Second Circuit" whether the operative date under Section 11 is November 29, 2000 or December 29, 2000. *Id.*

1. *The relevant date for purposes of Section 11 is November 29, 2000, the date the Registration Statement Became Effective.*

[4] I disagree with plaintiffs contention that there is any ambiguity as to which date is determinative for purposes of Section 11. Section 11 plainly states that it provides a civil remedy against certain individuals based on false statements or misleading omissions of material fact in any part of a registration statement *"when such part became effective."* 15 U.S.C. § 77k(a) (emphasis added); *see Nelson v. Paramount Communications, Inc.,* 872 F.Supp. 1242, 1246 (S.D.N.Y.1994) ("Section 11 by its own terms is limited to material omissions in parts of registration statements that were misleading 'when such part[s] became effective.' "); *see also* Thomas Lee Hazen, *The Law of Securities Regulation* 597 (4th ed. 2002) ("Section 11 by its terms applies to material misstatements and omissions in the registration statement 'when such part became effective.' Accordingly, when subsequent events make an effective registration statement misleading, section 11 does not apply.").

Plaintiffs provide no authority to support their assertion that liability can attach—*under Section 11* when events that occur after the effective date of the registration statement render statements therein misleading. Instead, plaintiffs conflate the issues of (1) whether defendants had a duty to disclose particular facts; (2) whether defendants had a duty to update information obtained subsequent to disclosure; and (3) which provision of the securities laws defendants would be liable under if they violated either duty.

It is clear that, under certain circumstances, companies must update information contained in an effective registration statement. In *SEC v. Manor Nursing Ctrs., Inc.,* 458 F.2d 1082, 1095 (2d Cir.1972), the Second Circuit held that "[p]ost-effective developments which materially alter the picture presented in the registration ***184** statement must be brought to the attention of public investors." (Pltf. Mem, 20.) Plaintiffs quote this language as support for their position that defendants were required to amend the registration statement. But the Second Circuit followed this sentence with a footnote, which explained that "[t]he way the new facts are brought to the attention of offerees as a matter of mechanics is by putting a sticker on the prospectus or supplementing it otherwise, not by amending the registration statement." *Manor Nursing Ctrs.,* 458 F.2d at 1096 n. 14 (citation omitted); *see also, Irving Bank Corp. v. Bank of New York Co.,* 692 F.Supp. 172 (S.D.N.Y.1988) (discussing this language in *Manor Nursing Ctrs*).

So a duty to update information in a registration statement does not itself create a duty to amend the registration statement. Plaintiffs' attempt to suggest otherwise by citing cases that do not involve Section 11 is not persuasive. *See e.g., S.E.C. v. Manor Nursing Centers, Inc.,* 458 F.2d 1082 (2d Cir.1972) (involved Section 17(a) of the Securities Act and Section 10(b) of the Exchange Act); *L.L. Capital Partners v. Rockefeller Center Properties, Inc.,* 921 F.Supp. 1174 (S.D.N.Y.1996) (involved Section 10(b) and 12(a)(2) of the Exchange Act). It does not follow that because a failure to update material information creates liability under other provisions of the securities code, it also creates liability under Section 11. Unlike Section 11, none of the other securities code provisions at issue in the cases cited by

plaintiff contain language specifying the point when liability will be determined.

Plaintiffs also argue that "[i]n the context of an express undertaking to update, as here, the Second Circuit has found an affirmative duty to amend the registration statement to reflect the occurrence of material events subsequent to the effective date," citing *Finkel v. Stratton Corp.,* 962 F.2d 169, 174 (2d Cir.1992). In doing so, plaintiffs mischaracterize *Finkel* and the relevant statutory scheme. In *Finkel,* the Second Circuit determined the date that the statute of limitations begins to run from for claims brought under Section 11 and Section 12(a)(2). The Circuit considered, and rejected, the Finkel plaintiff's claim that the statute of limitations for Section 11 began running on the date defendants filed a post-effective amendment to the registration statement, which incorporated a supplemental prospectus. *Finkel,* 962 F.2d at 172, 174. Plaintiffs had argued that the later date was appropriate because of SEC regulation S–K Item 512(a)(2), 17 C.F.R. § 229.512(a)(2), which requires that when shelf-registered securities are sold, the issuers must *amend the prospectus* to reflect changes arising after the effective date of the registration statement. *Id.* at 174. The Circuit found that the plaintiffs misread the impact and purpose of the regulation, which specifically applies to securities offered in a shelf registration and was intended to address the problems inherent in that type of transaction. *Id.* The Court held that the regulation had no relevance to the case before it. *Id.* It likewise has no relevance here. And *Finkel* itself certainly does not establish an affirmative duty to amend a registration statement. Rather, it recognizes that certain SEC regulations require that, under certain circumstances, the *information* contained in a registration statement must be updated. Finkel does not hold, state, or imply that if information necessary to make a registration statement not misleading is not provided to investors, Section 11 liability will result.

Therefore, for purposes of considering whether defendants are civilly liable to plaintiffs under Section 11, I will consider whether the registration statement/prospectus *at the time it became effective,* ***185** contained any untrue statements of material fact or omitted to state any material facts necessary to make the statements therein not misleading; the relevant date for plaintiffs' Section 11 claim is November 29, 2000.

2. *The relevant date for purposes of Section 12(a)(2) is a date on or after Friday, December 29, 2000 and on or before Wednesday, January 3, 2001.*

[5] The securities laws do not leave plaintiffs without recourse when events that occur after the effective date of a registration statement/prospectus render statements therein misleading. Section 12(a)(2) provides plaintiffs with what Section 11 does not—a cause of action against defendants based on their failure to disclose events that occurred after November 29, 2000.

"Unlike Section 11, Section 12(a)(2) 'does not specify the point in time to which materiality is related. However judicial interpretation makes the time of purchase the crucial moment for the determination of materiality.' " *In re Dreyfus Aggressive Groth Mutual Fund Litig.,* No. 98 CV 4318(HB), 2000 WL 1357509, at * 7 (S.D.N.Y. Sept.20, 2000) (Baer, J.) (quoting *Rosen v. Fidelity Fixed Income Trust,* 169 F.R.D. 295, 299 (E.D.Pa.1995)) (additional citations omitted). In most cases brought under Section 12(a)(2), the time of purchase is clear—it is the date that a plaintiff bought stock on a public exchange. But in the instant case, plaintiffs purchased Alliance stock in a stock-swap, pursuant to a merger agreement. Plaintiffs thus propose that the appropriate date for purposes of determining materiality is December 29, 2000, the date that the shareholders voted to approve the merger agreement. Certainly, I can fix the date no earlier.

[6] Defendants argue that I should—claiming that the effective date for purposes of Section 12(a)(2) is the effective date of the registration statement. Defendant's sole support for their position is *Freedman v. Value Health, Inc.,* 135 F.Supp.2d 317 (D.Conn.2001). In *Freedman,* the district court found that the relevant date for purposes of both Section 11 and Section 12(a)(2) claims was the date the registration statement/prospectus became effective. 135 F.Supp.2d at 317 n. 3. The opinion does not provide any rationale or cite any statutory or decisional law, and the court did not need to focus on whether developments after the effective date could have made statements therein misleading. Thus, *Freedman* is neither persuasive nor controlling and to the extent that it suggests that materiality for purposes of Section 12(a)(2) is determined as of the date a registration statement/prospectus is deemed effective, it is contrary to the reasoning of other opinions in this Circuit.

In fact, it is possible that the date of commitment was even later than December 29, 2000. The record is silent as to what happened in regards to the merger between Friday, December 29, 2000, when the shareholders voted to approve the merger, and Wednesday, January 3, 2001, when the completed merger was announced. No doubt the intervening

long holiday weekend contributed to a delay in the merger process—or even the announcement. But without knowing for sure when the merger was completed, it is impossible for me to determine the exact point the plaintiffs became committed to the sale—and thus "purchased" the Alliance stock.

It is clear from the merger agreement that the shareholder vote did not itself complete the merger. The agreement states that "[e]ach of MBI's and Alliance's obligations to complete the merger is subject ***186** to the satisfaction or waiver of specified conditions before completion of the merger." Adoption of the merger agreement by the affirmative vote of a majority of the holders of outstanding MBI common stock is one condition, but there are others, including (1) that the obligations of each company are subject to the other company's "representations and warranties that are qualified by materiality or as to a material adverse effect on Alliance or its business, condition, ... prospects [etc.] ... must be true and correct in all material respects, as of the effective time of the merger as though made at and as of the effective time of the merger ..."; and (2) that the terms of the Cooperative Development and Marketing Agreement between MBI and Chugai Pharmaceutical Co., Ltd., dated March 31, 1998, must not have been terminated, amended, modified or altered. (*See* Merger Agreement, p. 37–38, within the Prospectus at Ex. A to the Declaration of Mary D. Manesis ("Manesis Dec.").)

In addition to these enumerated conditions, the merger agreement states that it "may be terminated at any time prior to the completion of the merger, *whether before or after MBI's stockholder approval has been obtained,"* for a number of reasons, including: (1) by the mutual consent of the boards of directors of Alliance and MBI; (2) by MBI to allow MBI to enter into an agreement which MBI's board determines to be a superior proposal; and (3) for any reason, provided that upon such termination, the party terminating the merger agreement pays to the other party liquid damages as a "termination fee." *Id.* at 39–40 (emphasis added).

So the shareholder vote on December 29, 2000 was only one of several conditions that had to be met in order to complete the merger. Even after shareholder approval, MBI had the right to back out of the agreement for a number of reasons—or for no reason at all if it was willing to pay the termination fee. In light of these provisions, it appears that the shareholder vote itself did not legally commit the MBI stockholders to buy the Alliance stock. The "time of purchase"—and thus the appropriate date for determining materiality—may have been after December 29, 2000.

Determining materiality from the point of legal commitment for purposes of Section 12(a)(2) is consistent with Second Circuit law determining the point at which materiality is determined for purposes of Rule 10b–5.[4] In *Castellano v. Young & Rubicam, Inc.,* 257 F.3d 171 (2d Cir.2001), the Second Circuit determined that for purposes of Section 10(b) and Rule 10b–5 "the materiality of the information misstated or withheld is determined in light of what the defendants knew at the time the plaintiff committed himself to sell the stock." *Castellano,* 257 F.3d at 181 (quoting *Michaels v. Michaels,* 767 F.2d 1185, 1195 (7th Cir.1985)). The Circuit's holding in *Castellano* reaffirmed the reasoning of *Radiation Dynamics, Inc. v. Goldmuntz,* 464 F.2d 876, 890–91 (2d Cir.1972), in which the Circuit approved a jury instruction given by the Honorable Milton Pollack regarding the proper time for determining ***187** materiality. *See Castellano,* 257 F.3d at 181. In *Radiation Dynamics,* the Second Circuit held that Judge Pollack correctly instructed the jury that the time of a "purchase or sale" within the meaning of Rule 10b–5 is the time when the parties to the transaction *are committed to one another. Radiation Dynamics,* 464 F.2d at 891. Judge Pollack further instructed that: " '[c]ommitment' is a simple and direct way of designating the point at which, in the classical contractual sense, there was a meeting of the minds of the parties; it marks the point at which the parties obligated themselves to perform what they had agreed to perform even if the formal performance of their agreement is to be after a lapse of time...." *Id.* at 891.

This analysis is also consistent with the approach used in the context of claims brought under Section 16(b) of the Securities Exchange Act of 1934. 15 U.S.C. § 78p(b). The definition of "purchase and sale" used by Courts in analyzing claims under Section 16(b) is substantially similar to the definition under Section 10(b). Section 16(b) prohibits a purchase and sale or sale and purchase of an issuer's stock by officers, directors, or beneficial owners of more than 10% of any class of securities of the issuer—in other words, corporate "insiders"—within any period of less than six months. In determining the point at which the insider purchased or sold a security, courts look at the context of the transaction to determine when the insider became irrevocably bound to dispose of his or her securities. *Riseman v. Orion Research, Inc.,* 749 F.2d 915, 918–919 (1st Cir.1984); *Jammies Intern. Inc. v. Nowinski,* 700 F.Supp. 189, 193 (S.D.N.Y.1988). In *Portnoy v. Revlon, Inc.,* 650 F.2d 895 (7th Cir.1981), the

Seventh Circuit affirmed the district court's determination that the point of sale for the purposes of the transaction at issue in the case was the closing date of the merger through which the insider obtained shares in a stock exchange. The Seventh Circuit found that the sale did not occur until the closing date of the merger, because the merger agreement contained significant conditions precedent that could have blocked consummation of the transaction. *Id.* at 900. The Court noted the fact that the insider had lost control of the transaction after a certain point, but explained: "That one party has completed whatever steps it can take does not finalize the transaction if significant obstacles to closing remain to be faced. There was no irrevocable commitment to exchange shares until the significant conditions precedent to closing were fulfilled." *Id.* at 901. The reasoning in *Portnoy* is applicable to the instant case, as the parties' obligation to exchange their stock was subject to the fulfillment of significant conditions under the merger agreement.

So while there is no clearly controlling authority that directs that the effective date here for purposes of Section 12(a)(2) is after the shareholder vote, the persuasive authority suggests the possibility. Plaintiffs do not allege that the effective date is any later than December 29, 2000, but perhaps they should have. While I am not interested in advancing arguments that the parties themselves have not made, I am also aware that under the circumstances of this case, where developments in the clinical trial were happening at the same time as the merger process was occurring, the effective date is a vital determination. Were I to grant summary judgment in favor of defendant based on an analysis of materiality as of December 29, 2000, subsequent arguments on appeal might address the question of whether the result would have been different if the materiality was determined as of a later date. To avoid such a scenario, and to give the nonmoving plaintiffs the benefit of ***188** all possible favorable inferences, I will proceed with the analysis by assuming that plaintiffs could establish at trial that the appropriate relevant date was Wednesday, January 3, 2001. I leave it to the parties on pre-trial motions to provide the necessary factual basis for me to determine what point on or after Friday, December 29, 2000 and on or before Wednesday, January 3, 2001 is the appropriate relevant date for purposes of determining materiality under Section 12(a)(2).

D. Materiality of Alleged Omissions in Alliance's Statements

Plaintiffs allege that defendants violated Section 11 and Section 12(a)(2) by making four statements in the Registration Statement/Prospectus that were false and/or misleading due to material omissions. I consider each of these statements in turn. In evaluating each, I apply the standard, noted above, that in order for an omission to meet the materiality requirement, "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 made available." *TSC Industries, Inc., v. Northway,* 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976) *quoted in In re Time Warner Sec. Litig.,* 9 F.3d 259, 267 (2d Cir.1993). Materiality is a mixed question of law and fact. *Id.* at 450, 96 S.Ct. 2126. Only when the omissions are so obviously important or unimportant to a reasonable investor that "reasonable minds cannot differ on the question of materiality" is the issue appropriately resolved as a matter of law by summary judgment. *Id.* (citations omitted).

1. *Phase 3 Oxygent Clinical Trials*

[7] The Registration statement made the following statements regarding Oxygent:

> Oxygent is a temporary oxygen carrier, being evaluated in a Phase 3 clinical human trial with cardiac patients. In September 2000, Alliance announced that an initial analysis of data from a Phase 3 clinical trial in Europe indicated that Oxygent significantly reduced the need for donor blood in the target population. Oxygent is a blood substitute that uses PFCs as raw materials, instead of human or natural blood. It is being developed to reduce or eliminate the need for human blood transfusions during elective surgeries where substantial blood loss is common. Phase 3 trials are typically the final human studies required prior to requesting marketing approval from a U.S. or foreign regulatory agency.

(SAC, 68.) Plaintiffs allege that the preceding statement was misleading because defendants failed to disclose: "(a) the status of the United States Oxygent Phase 3 clinical trial, and (b) that patient enrollment in the United States' study of

Oxygent begun in December 1999 contained imbalances in the control group, necessitating its immediate and indefinite suspension." (SAC, 69.) [5]

***189** There is no general duty to provide "status reports" regarding ongoing activities. But plaintiffs argue that any undesirable results that arise during clinical testing are necessarily material, citing *In re Carter–Wallace Inc. Sec. Litig.,* 150 F.3d 153, 157 (2d Cir.1998) and *In re Regeneron Pharmaceuticals Sec. Litig.,* 1995 WL 228336, at *3 (S.D.N.Y. Mar.10, 1995). Of course, in both *Carter–Wallace* and *Regeneron,* the defendants had made positive statements regarding the safety of their products, which were rendered potentially misleading when later data undermined their claims. *See Carter–Wallace Inc.,* 150 F.3d at 155–157 (statement advertising a drug's safety record and stating that "no life-threatening liver toxicities or blood dyscrasias" had been attributed to its use became potentially materially misleading when defendant learned that drug caused fatal bone-marrow failure in some patients); *Regeneron,* 1995 WL 228336, at *2–4 (statement that drug was "safe and well tolerated" and "produced few side effects" became potentially materially misleading when defendants learned of severe adverse side effects compromising the study). Here, the Prospectus contained no statements regarding the preliminary results or progress of the United States cardiac clinical trial, and no predictions that the positive results of the European clinical trial would be repeated.

Moreover, in *Carter–Wallace,* in the context of determining whether the positive financial projections were rendered misleading by the occurrence of adverse events, the Second Circuit held that the defendant drug company was not required to disclose reports of illnesses until there was statistically significant evidence that the illnesses were "caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings." 150 F.3d at 157. The Second Circuit thus implicitly recognized that not every adverse effect in a clinical trial is automatically material, and that causation, as well as statistical significance, is key.

The statement at issue contains no report on the results of the ongoing cardiac clinical trial that could be rendered misleading without reports of continuing developments. All it says is that Oxygent is currently being evaluated. That statement was absolutely and indisputably correct, and it continued to be correct until January 8, 2001. Moreover, there is no evidence that anyone believed, or even thought, that the evaluation would have to terminate prior to January 4th or 5th, 2001, when Dr. de Haan first saw a statistical analysis of the data showing that all patients in the Oxygent trial group were at increased risk of stroke.

Because there is no general duty to update with the "status" of a trial, and no express statement that the trial was progressing well, plaintiffs can only prevail if the statements regarding Oxygent, taken as a whole, became misleading when negative developments that caused a change in the clinical protocol and the commencement of special evaluative efforts were not disclosed. In other words, summary judgment is not appropriate if reasonable minds could conclude that the statement that "Oxygent is being evaluated in a Phase 3 trial, the final step before regulatory approval; the results of a Phase 3 trial in Europe went well," became misleading ***190** when adverse developments became apparent, leading to alteration in the clinical protocol.

Plaintiffs fail to raise a disputed issue of fact on this point under Section 11. All parties agree that as of November 29, 2000, the relevant date for purposes of Section 11 liability, the only potentially adverse information regarding the cardiac clinical trials was a higher incidence in adverse neurological events between the control group and the Oxygent group that was not statistically significant. It is undisputed that the Alliance medical team, with the blessing of the independent DSMB, continued with the trial without any alterations in protocol. There is no evidence in the record that there was any plan, or any need, to end the evaluation of Oxygent at that time, or even to alter the circumstances under which it was being evaluated. And there is no evidence that defendants had reason to be concerned about the viability of the drug. Plaintiffs have thus failed to offer any evidence that creates a genuine issue of material fact as to whether the statement above was rendered false or misleading by incidents which occurred on or before November 29, 2000. They have no viable Section 11 claim on this point.

[8] Under Section 12(a)(2), the question is a close one. However, we are dealing here with an omission, and only omissions so obviously important or unimportant that "reasonable minds could not differ on the question of materiality" are properly resolved as a matter of law by summary judgment. *TSC Indust., Inc.,* 426 U.S. at 450, 96 S.Ct. 2126 (citations omitted). Here, reasonable minds can differ. Alliance disclosed that it was in Phase 3 (final phase) trials and that it had enjoyed positive results in a Phase 3 trial in Europe. The fact that Alliance reported the favorable results

of the earlier European general surgery Phase 3 trial is not a prediction that the results of the ongoing United States cardiac Phase 3 trial would be similar. *See Zucker v. Quasha,* 891 F.Supp. 1010, 1015 (D.N.J.1995) (no affirmative statement subjecting defendants to liability when prospectus contained statement of historical performance without predicting future performance); *In re Convergent Tech. Sec. Litig.,* 948 F.2d 507, 513 (9th Cir.1991) (accurate reporting of past results does not imply similar future results). In fact, Alliance was careful to say that adverse developments could occur at any time. (See Prospectus, p. 11–12, Ex. 1 to Manesis Dec.) However, developments adverse enough to cause a change in the clinical protocol were not just possible—they were actually occurring as the date for the shareholder vote approached.

Defendants claim that this change in protocol was nothing for investors to be concerned about, and assert in their 56.1 Statement that "modifying exclusion or inclusion criteria for a clinical trial based on accruing safety data is not uncommon." (Def. 56.1, 52, citing the deposition testimony of Dr. Dittrich, 30, Manesis Dec., Ex. L.) But this statement is far too general to be helpful to defendants. Something can be "not uncommon" and yet be material when viewed against the totality of the circumstances.

On the other hand, the change in protocol does not by itself establish the liability of the defendants. I am less than impressed by plaintiffs' suggestion, raised for the first time in their opposition to summary judgment, that Alliance's failure to notify MBI stockholders of the December 26, 2000 decision to change the eligibility criteria for the Oxygent Phase 3 clinical trial was itself a violation of Section 12(a)(2), because the Prospectus warned that:

> ***191** Alliance cannot predict how long its preclinical and clinical trials will take or whether they will be successful. The rate of completion of the clinical trials for its products depends on many factors, including obtaining adequate clinical supplies and rate of patient recruitment. Patient recruitment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites and the eligibility criteria for patients who may enroll in the trial.

(Prospectus, p. 12.) Plaintiffs argue that the new exclusion criteria "may have doomed the Phase 3 clinical trial by making it 'undersized,' " and claim that this would make the statement above—and presumably the original statement that Oxygent was being evaluated—misleading. The only evidence that plaintiffs cite to support their claim is the minutes of a telephone conference report from January 9, 2001 in which medical researchers from Alliance spoke with Medical Review personnel from the Center for Biologics Evaluation and Research. (Manesis Dec., Exhibit S.) The minutes indicate that, during the call, one of the reviewing doctors mentioned that, had the study proceeded under the modified exclusion criteria, "the study might be considered undersized." *Id.* at 3. This statement was not only indefinite and hypothetical at the time is was made, but it also fails to create a genuine issue about whether Alliance had any information on or before January 3, 2001 that suggested that the size of the patient population was problematic or that the Oxygent trial would fail to proceed. To the contrary, Alliance offers evidence that at the time the trial was suspended two-thirds of the patients projected for inclusion in the study had been enrolled. Plaintiffs have failed to offer evidence that, prior to January 4, 2001, defendants had any information that would have made the risk factor regarding patient enrollment misleading.

Plaintiffs will have their day in court, but they obviously face a much greater burden in convincing a trier of fact of defendants' liability than they have overcome here by defeating defendants' motion for summary judgment. Plaintiffs must show that, under the totality of the circumstances, defendants were aware, as of the materiality date, that the increase in adverse events cast doubt on the previous positive results of Oxygent. I remind plaintiff that they will not prevail in establishing materiality with arguments based in hindsight. *See e.g., In re Union Carbide Class Action Sec. Litig.,* 648 F.Supp. 1322, 1327 (S.D.N.Y.1986). As the Honorable Edward Weinfeld explained: "The determination of materiality is to be made upon all the facts as of the time of the transaction, and not upon a 20–20 hindsight view long after the event." *Spielman v. General Host Corp.,* 402 F.Supp. 190, 194 (S.D.N.Y.1975) (footnote omitted), *aff'd per curiam,* 538 F.2d 39 (2d Cir.1976) *quoted in Union Carbide,* 648 F.Supp. at 1327 and *Ganino v. Citizens Utils. Co.,* 228 F.3d 154, 165

(2d Cir.2000). Plaintiffs will not be able to establish liability by showing that defendants had material information as of January 4 or 5 after the latest possible relevant date for purposes of Section 12(a)(2).

Similarly, defendants will not prevail by proving that the concerns about Oxygent that developed during the United States Phase 3 cardiac clinical trial were addressed months or years after the fact. The trier of fact will be focused only on whether, as of the relevant date, defendants failed to disclose information that would have been viewed by the reasonable investor as having significantly altered the total mix of information made available regarding Oxygent.

***192** Again, I note that this is a very close case—one that approaches resolution as a matter of law. But because I find that under the totality of the circumstances presented reasonable minds could differ as to the materiality of defendants' omissions regarding adverse developments in the Oxygent cardiac clinical trial, I find that this dispute must be resolved by a trier of fact.

2. *Overstatement of Alliance's Capital Resources*

The Registration statement made the following statements regarding Alliance's capital resources:

> The costs of Alliance's current clinical trials are high. Alliance believes that its existing capital resources, including investments by Baxter Healthcare Corporation, will satisfy its capital requirements through fiscal 2001.

(SAC, 70.) Plaintiffs allege that this statement was materially false and misleading because "(a) defendants had no good faith or reasonable basis to state that 'Alliance believes that its existing capital resources, including investments by Baxter Healthcare Corporation, will satisfy its capital requirements through fiscal 2001,' as the failure of the Phase 3 trials jeopardized future capital infusions; (b) defendants failed to disclose: (i) the risks concerning the United States' Phase 3 clinical trial; and (ii) that patient enrollment in the United States' Study of Oxygent begun in December 1999 contained imbalances in the control group, necessitating its immediate and indefinite suspension." (SAC, 71.)

Defendants argue that this statement is a "forward-looking" expression of optimism balanced by specific warnings in the Prospectus, which is not actionable under the "bespeaks caution" doctrine and the Safe Harbor provision of the Private Securities Litigation Reform Act ("PSLRA"). Under the bespeaks caution doctrine, "a misstatement or omission [related to a forward-looking statement] will be considered immaterial if cautionary language is sufficiently specific to render reliance on the false or omitted statement unreasonable." *In re Independent Energy Holdings PLC Sec. Litig.,* 154 F.Supp.2d 741, 755 (S.D.N.Y.2001). In other words, when a prospectus—read as a whole—bespeaks caution of the very risk that plaintiffs complain was not disclosed, a plaintiff can not successfully claim that the forward-looking statement was misleading. *Olkey v. Hyperion 1999 Term Trust, Inc.,* 98 F.3d 2, 7–9 (2d Cir.1996); *In re Ultrafem Inc. Sec. Litig.,* 91 F.Supp.2d 678, 696 (S.D.N.Y.2000). And the Safe Harbor provision of the PSLRA, which was modeled in part after the bespeaks caution doctrine, grants protection to forward-looking statements that prove to be incorrect if: (a) the forward-looking statement is (i) identified as forward-looking and accompanied by meaningful cautionary statements or (ii) immaterial; or (b) the plaintiff cannot prove that the forward-looking statement, even if unaccompanied by cautionary language, was made with actual knowledge that the statement was false or misleading. 15 U.S.C. § 77(2)(c)(1); *see also In re Independent Energy,* 154 F.Supp.2d at 755.

[9] But neither the bespeaks caution doctrine nor the Safe Harbor provision of the PSLRA protects a defendant from liability if a statement was knowingly false when made. *Id.* at 756–757. Even if defendants had adequately warned of the possibility of funding problems resulting from delays in clinical trials, they would not be protected from liability if they knew the statement was false or misleading at the time it was made. *In re Prudential Sec. Inc. Ltd. Partnerships Litig.,* 930 F.Supp. 68, 72 (S.D.N.Y.1996) ("The doctrine of bespeaks caution provides no protection to someone who warns his hiking ***193** companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away.") Because plaintiffs have alleged that the defendants knew that the statement was false at the time it was made (SAC, 34.), it is irrelevant whether defendants warned of potential problems. If defendants did not actually believe that Alliance's capital resources would satisfy its capital requirements through fiscal 2001, because of anticipated problems with Baxter Healthcare or for any other reason, this statement would be false or

misleading. *Time Warner,* 9 F.3d at 266; *In re Oxford Health Plans, Inc.,* 187 F.R.D. 133, 141 (S.D.N.Y.1999) (opinion may be actionable if it is without basis in fact or if the speaker was aware of facts undermining its accuracy).

[10] Plaintiffs fail, however, to offer any evidence that defendants knew that the statement was false when made, on November 29, 2000. Moreover, even assuming *arguendo* that this statement is not protected by the Safe Harbor Provision of the PSLRA or the bespeaks caution doctrine, plaintiffs have not created a genuine issue of material fact as to whether this statement became misleading at any point before January 3, 2001.

Plaintiffs' allegations here are similar to those examined in Section II D(2) *supra,* but here the issue of materiality can be resolved as a matter of law. Plaintiffs were able to defeat summary judgment as to the Oxygent claims because the statements regarding the drug, *taken as a whole,* could have become misleading when defendants failed to disclose information that undermined the positive impression of the success of the drug. Here, the statement at issue does not directly concern the results or progress of the clinical trials of Oxygent. Adverse developments in the cardiac clinical trial would not necessarily undermine Alliance's funding through June 30, 2001. Plaintiffs offer no evidence that, on or before January 3, 2001, defendants knew that the results of the Oxygent cardiac clinical trial would jeopardize its capital resources. There is no evidence in the record that any Alliance employee even questioned the continued progress of the Oxygent clinical cardiac trial until, at the earliest, January 4, 2001. Adverse developments in the trial raise a genuine issue of material fact as to the potentially misleading nature of the statements about Oxygent itself, but they are too attenuated to create a genuine issue of material fact that the company would not be able to satisfy its capital resources for the next five months. Plaintiffs cannot bootstrap a claim by asserting that evidence of adverse developments in the clinical trial necessarily evidenced an inability to meet that fiscal year's funding needs.

This statement is similar to the ones made by the defendant in *Carter–Wallace,* discussed in Section II. D. (2), *supra,* in which the drug manufacturer defendant stated that sales of its product were expanding, that the rate of growth was expected to continue, and that the company expected to receive licensing royalties. In *Carter–Wallace,* the Second Circuit rejected the plaintiffs' claim that defendants' financial statements became materially misleading when defendants became aware that the product had caused three deaths, holding that the statements "did not become materially misleading until Carter–Wallace had information that ... [the drug product] had caused a statistically significant number of ... deaths and therefore had reason to believe that the commercial viability of [the drug product] was threatened." *Id.* at 157. In the instant case, there is no evidence that defendants ever had statistically significant evidence that Oxygent caused—as opposed to being correlated ***194** with —a statistically significant number of adverse reactions. And it was not until after the relevant date for both Section 11 and Section 12(a)(2) that defendants had information that led them to voluntarily suspend the clinical trial and thus possibly jeopardize future funding. Plaintiffs claims based on this statement fail because there is no genuine issue of material fact as to whether defendants had information during the relevant time period that, by its omission, made the statement regarding funding in the registration statement/prospectus false or misleading.

Furthermore, while the materiality of the alleged omission is appropriately determined at the point of the transaction, and not in hindsight, I note that, despite plaintiffs' claim that Baxter "eliminate[d] or substantially curtail[ed] its funding to Alliance," there is no evidence in the record to prove that this occurred. Indeed, there is no evidence that Alliance ever concluded that it could not satisfy its capital requirements through fiscal 2001. To the contrary, Alliance press reports indicate that Baxter Healthcare continued to invest in Alliance even after suspension of the Oxygent trial. Alliance's fiscal year ended on June 30 of each year. (Alliance's 2000 Annual Report, Ex. B to Manesis Dec., p. 18.) On March 18, 2001, Alliance issued a press release in which it stated that, due to changes in the timeline for Alliance's clinical and regulatory plans, Baxter and Alliance had mutually agreed that Baxter Healthcare's scheduled $15 million stock purchase would be delayed from March 15 to May 1. (March 13, 2001 Press Release, Ex. E to Manesis Dec., p. 1.) But Alliance further stated that no further changes to the original agreement were contemplated, and quoted the Corporate Vice President of Baxter Healthcare as stating: "Baxter is committed to working with Alliance to determine the appropriate next steps for continuing development of Oxygent." There is no evidence in the record to suggest that the stock purchase did not occur on May 1, 2001, or that any other developments occurred between March 13, 2001 and June 2001 that prevented Alliance from meeting its working capital requirements for fiscal year 2001. And additional reports indicate that, at a minimum, Alliance continued its investment relationship

with Baxter well into fiscal 2002. (January 17, 2002 Press Release, Ex. F to Manesis Dec. (reporting that Baxter made an additional investment of $2 million in Alliance convertible preferred stock, which was a milestone payment under a previously reported $19 million obligation); March 26, 2002 Press Release, Ex. G to Manesis Dec. (reporting that Alliance and Baxter representatives were planning a European Phase 3 study of Oxygent).)

3. *Merger Agreement*

[11] Plaintiffs also point to the text of the Merger Agreement between MBI and Alliance, which was contained in the Prospectus. Plaintiffs argue that Alliance represented in the Merger Agreement that:

> None of the information supplied or to be supplied by the Purchaser for inclusion in the Proxy Statement/ Prospectus will at the time of the mailing of the Proxy Statement/ Prospectus to stockholders of the Company or at the time of the meeting of such stockholders to be held in connection with the Merger, contain any untrue statement of a material fact or will omit to state any material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they are made, not misleading.

(SAC, 73.) Plaintiffs allege that this statement was materially false and misleading ***195** because defendants failed to disclose: "(a) that patient enrollment in the U.S. Study of Oxygent begun December 1999 contained imbalances in the control group, necessitating its immediate suspension; and (b) that the Company did not have enough capital to satisfy its funding requirements through 2001." (SAC, 73.) Plaintiffs allegations here are nothing more than a reiteration of the claims examined in Section II. D(1) and II. D(2), *supra.*

This language, as defendants explain in their reply memorandum, is required by the SEC in Form S–4 registration statements. It is simply a statement by defendants that they will comply with the law; it does not provide plaintiffs with an additional cause of action.

4. *MBI's Optison Partnerships and Settlement of Patent Litigation*

Finally, in regard to Optison, plaintiffs allege that defendants failed to disclose the existence or terms of a material agreement between MBI and Sonus, its "only viable competitor in the Asian Countries." (SAC, 8, 13.) Plaintiffs allege that this omission made the statements in the Registration Statement material, because the Registration statement "painted a gloomy picture of Chugai's interest in developing Optison, and emphasized the risks of patent litigation." *Id.* at 13. Specifically, the Registration Statement, under "Risk Factors" of MBI, stated:

> MBI HAS LIMITED CONTROL OVER ITS MARKETING PARTNERS AND THEIR ABILITY TO PRODUCE ROYALTY INCOME FOR MBI. MBI does not manufacture products and does not have and does not intend to develop its own marketing organization. MBI relies instead on its corporate partners to manufacture, market, and sell Optison ... Chugai has exclusive distribution rights for Optison in Japan, Taiwan and South Korea.
>
> [Chugai has] complete control over all aspects of product development, manufacturing and marketing of Optison in [its] territories. Therefore, MBI is dependent on [Chugai's] product development, regulatory and manufacturing capabilities, marketing efforts, resources and commitment to Optison ... Chugai may not market the licensed products effectively or at all.
>
> If MBI's partners were not able to alter Optison or their manufacturing processes to avoid conflicts with third-party patents, they would have to terminate the commercialization of Optison or pay royalties to the holders of the patents. Patent litigation can be very expensive and the result uncertain. MBI may not have the financial resources to resolve additional patent conflicts. In addition, patent conflicts may cause Mallinckrodt [MBI's sales agent for the United States and Europe] or Chugai to divert resources away from developing and marketing Optison.

(SAC, 75–77.) Plaintiffs contend that the "list of horribles" quoted above was false and misleading because defendants failed to disclose: "(a) that MBI cleared the way for the sale of Optison in the Far East Territories by entering into the Sonus

Agreement; and (b) Chugai had demonstrated its continued commitment to development [sic] and market Optison by making two million dollar non-refundable license payments plus royalties to Sonus to develop and market Optison in the Far Eastern Territories." *Id.* at 77.

[12] Defendants respond to this allegation by arguing that: "Alliance had no duty to disclose the parties' discussions and negotiations regarding the Sonus License Agreement prior to the time that MBI consummated the agreement in early ***196** January 2001." (Def. Mem., 27.) But it is clear that the law does not require that a contract be finalized in order for it to be material. In *SEC v. Texas Gulf Sulphur Co.,* the Second Circuit held that material facts include those that "affect the probable future of the company and [that] may affect the desire of investors to buy, sell, or hold the company's securities." 401 F.2d 833, 849 (2d Cir.1968) (en banc). An event need not be finalized to be material. "When contingent or speculative events are at issue, the materiality of those events depends on "a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity." " *Castellano v. Young & Rubicam, Inc.,* 257 F.3d 171, 180 (2d Cir.2001) (quoting *Basic Inc. v. Levinson,* 485 U.S. 224, 238, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988) (quoting *Texas Gulf Sulphur Co.,* 401 F.2d at 849)). So the fact that the Sonus License agreement was not finalized until early January 2001 is not, as defendants claim, "fatal" to plaintiffs' case.

[13] Defendants argue in the alternative that, even if the Sonus License Agreement had existed as of the relevant date, the statement above was not rendered misleading because of the agreement. Defendants assert that there is no evidence in the record that, as a result of the agreement, (1) "MBI did *not* rely on its product partners with respect to Optison," (2) "there was any guarantee that [its product partners] would market Optison effectively," or (3) "there was *not* the possibility of future patent disputes regarding Optison." (Def.Mem., 29) (emphasis in original). Defendants correctly observe that there is no evidence in the record of these facts or any other facts that would make the statement overtly false. Nevertheless, plaintiffs have raised a genuine issue of material fact as to whether the above statement was rendered misleading by the Sonus deal.

I agree with defendants' contention that plaintiffs overstate their case by referring to the warnings as a "parade of horribles." (Pltf.Mem., 11.) But defendants did provide relatively detailed information in the Prospectus about the relationship between MBI and Chugai, the hurdles faced by Chugai, and the threat of patent litigation. In light of the fact that MBI and Mallinckrodt had settled claims in May 2000 brought by Sonus and Nycomed Amersham plc for patent infringement based on MBI's sales of Optison in the United States and Europe, a reasonable investor could have been concerned, based in part on the statement above, that sales of Optison were threatened by the possibility that Sonus would bring a claim for patent infringement in other territories. While the Sonus License agreement did not forestall the possibility of all patent litigation regarding Optison in the Chugai territories, it did address the threat of a competitor with a known interest in bringing claims. And while receipt of any money under the agreement was conditioned on the successful completion of Sonus's pending patent applications, the fact that Chugai agreed to pay Sonus at least one million dollars before the patents were approved could suggest to a reasonable factfinder that the benefits conferred in the deal were valuable, even though Sonus could not guarantee successful marketing of Optison. Furthermore, a reasonable factfinder might conclude that the fact that Chugai had agreed to invest one to two million dollars in an effort to advance the marketing of Optison could render the statement that "Chugai may not market the licensed products effectively or at all" materially misleading.

There is no evidence in the record that negotiation of the Sonus License Agreement ***197** began before November 29, 2000, so there is no genuine issue of material fact as to (1) whether the balancing of the probability and the anticipated magnitude of the event weighs in favor of materiality; or (2) whether the statement was false or misleading at the time the Registration Statement became effective. There is thus no factual basis in the record before me for a Section 11 claim. I thus dismiss this claim.

But plaintiffs have raised a genuine issue of material fact as to whether, at some point before January 3, 2001, (1) the balancing of the probability and the anticipated magnitude of the event weighs in favor of materiality; and (2) the fact of the advanced negotiations of the Sonus License Agreement made the statement in the Prospectus about Chugai and the threat of patent infringement materially misleading. A reasonable investor might have found that the Sonus License Agreement significantly altered the total mix of information made available. *TSC Indus., Inc.,* 426 U.S. at 449, 96 S.Ct. 2126. The omission of this information is not so obviously unimportant to a reasonable shareholder that reasonable minds cannot differ on the question of materiality. *Id.* at

450, 96 S.Ct. 2126. Summary judgment is thus inappropriate as to plaintiffs' claim under Section 12(a)(2) based on this statement.

D. Controlling Person Liability Under Section 15

[14] Liability under Section 15 requires an underlying violation of Section 11 or Section 12(a)(2). I have granted summary judgment in favor of defendants on plaintiffs' Section 11 claims as to all four allegedly misleading statements and on two of plaintiffs' four Section 12(a)(2) claims. Because the plaintiffs still have the opportunity to prevail on their Section 12(a)(2) claim as to two allegedly misleading statements, I deny summary judgment on plaintiffs' Section 15 claims based on these underlying claims.

III. CONCLUSION

This constitutes the decision and order of the Court.

All Citations

279 F.Supp.2d 171

Footnotes

1 Plaintiffs respond to this factual assertion by stating that “Plaintiffs admit that on January 3, 2001, defendants issued a press release stating the foregoing; defendants have produced no evidence, however, establishing same as fact.” (Plaintiffs' Response to Defendants' 56.1 Statement (“Pltf.Resp.”), 5.) Yet plaintiffs themselves include this fact as an allegation in their Second Amended Complaint. (*See* Plaintiffs' Second Amended Complaint (“SAC”), p. 67.) And throughout their Memorandum in Opposition to Defendants' Motion for Summary Judgment, plaintiffs refer to the their vote to approve the merger on December 29, 2000. As MBI shareholders, plaintiffs are clearly in a position to provide evidence contradicting this fact if it is incorrect, and their failure to respond to the Defendant's 56.1 Statement with a citation to evidence—as well as the telling fact that plaintiffs themselves alleged the same fact—indicates that plaintiffs have no legitimate dispute as to the accuracy of this fact.

2 Plaintiffs have not offered evidence to document these stock prices. More significantly, plaintiffs have not offered any evidence that defendants reported that the company might not have sufficient working capital to meet its commitments for the fiscal year. *See* Section II, D(2), *infra.*

3 As of this date, I have not been advised by either party about any developments in these discussions.

4 Rule 10b–5, 17 C.F.R. § 240.10b–5, promulgated under Section 10b of the Securities Exchange Act of 1934, 15 U.S.C. § 78j, provides a cause of action when a defendant, in connection with the purchase or sale of securities, “makes any untrue statement of material fact or ... omit[s] 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.” The determination of whether a fact is material is the same for actions under Rule 10b–5 as for actions under Section 11 and Section 12(a)(2). *Crewnick Fund v. Castle,* 1993 WL 88243, at *6 (S.D.N.Y. March 24, 1993).

5 I presume that when plaintiffs refer to “imbalances in the control group,” they mean imbalances between the control group and the treatment group. There is no evidence of any imbalances within the control group itself that led to the termination of the trial. However, I note the possibility that plaintiffs are trying to advance a theory that there was a problem with the control group. *See* Pltf. Mem., 27 (where plaintiffs argue, without further explanation, that “even if the significance of the failed Phase 3 tests was not determined until after the Merger, defendants did not even mention the possibility of problems with control groups.”) But the only evidence regarding the control group in the record is the fact that there were an unusually low incidence of strokes in the control group, which is a fact that harms plaintiffs' case rather than helps it (without the low incidence in the control group, there might not have been a statistically significant difference in adverse events between the two groups). Without any evidence that the trial was suspended because of problems with the control group, I will not spend additional time trying to divine what plaintiffs' choice of language means.