UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE SANOFI-AVENTIS SECURITIES LITIGATION

MEMORANDUM OPINION AND ORDER

07-cv-10279 (GBD)

08-cv-00021 (GBD)

GEORGE B. DANIELS, United States District Judge:

Plaintiffs City of Edinburgh Council on behalf of the Lothian Pension Fund ("Lothian"), New England Carpenters Guaranteed Annuity Fund (" N.E. Carpenters"), the City of Taylor General Employees Retirement System on behalf of itself and all others similarly situated, and Carrie Smith, individually and on behalf of all others similarly situated (collectively, "plaintiffs") bring this action against the French pharmaceutical company Sanofi-Aventis ("Sanofi") and individual defendants Jean-Francois Dehecq, Gerard Le Fur, Hanspeter Spek, Marc Cluzel, Jean-Pierre Lehner, Douglas A. Greene, and Jean-Claude Leroy (collectively, "the individual defendants"). Plaintiffs allege violations of Section 10(b) of the Securities and Exchange Act of 1934, 15 U.S.C. § 78j(b) (the "Exchange Act"), and Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder and "control person" liability pursuant to Section 20(a) of the Exchange Act. Before this Court is defendants' motion to dismiss plaintiffs' claims pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defendants' motion is granted.

MATERIAL ALLEGATIONS

Lothian and N.E. Carpenters, lead plaintiffs in this action, purport to represent a class of all individuals and entities that purchased Sanofi securities from March 1, 2005 through June 13,

2007. Plaintiffs' allegations relate to defendants' research activities and attempt to market a drug called "rimonabant" used to treat obesity and related illnesses. The following facts taken from the complaint are assumed to be true and are construed in the light most favorable to plaintiffs. See Blue Tree Hotels Investment v. Starwood Hotels & Resorts Worldwide, Inc., 369 F.3d 212, 217 (2d Cir. 2004).

Sanofi conducted four advanced or "phase III" clinical trials (the "RIO Studies") to test rimonabant's potential in treating obesity prior to the class period. Id. at ¶ 4. The results from the RIO Studies and other clinical trial data were made available to the public in numerous press releases, medical journals, and during conference calls with market analysts. See, e.g., Delaration of S. Christopher Provenzano In Support of Defendants' Motion to Dismiss ("Provenzano Decl."), Ex. A (article reporting RIO Studies data published in The Lancet on April 16, 2005); id. at Ex. B (New England Journal of Medicine article reporting RIO-Lipids study on Nov. 17, 2005); id. at Ex. C (Rio North America study data published in the Journal of the American Medical Association on Feb. 15, 2006); id. at Ex. D (Rimonabant in diabetes study data published in The Lancet on Nov. 11, 2006). Those clinical studies provided positive data regarding treatment of obesity and related illnesses among patients treated with rimonabant as well as "serious safety signals" concerning behavioral side effects associated with the drug. See, e.g., Complaint at ¶¶ 26, 31, 33, 66-68, 70, 80. Based on both the clinical findings and the likely demand for the drug, defendants also predicted sales of the rimonabant amounting to € 3.2 billion in 2010 and € 4.5 billion in 2015. Id. at ¶ 72.

On February 17, 2006, after submitting its safety data to the Food and Drug Administration ("FDA"), Sanofi received an "approvable letter" from the regulators with respect

to the use of rimonabant in obesity treatment and a non-approvable letter concerning use of the drug as a smoking cessation aid. Id. at ¶ 24. In that correspondence, the FDA requested that Sanofi apply a new analytical framework to the RIO Studies data and submit supplemental findings to address the agency's concerns that use of rimonabant in treating obesity might be associated with higher rates of suicidality and other mood disorders. Id. Sanofi publicly disclosed its receipt of the approvable letter and informed potential investors the company would "continue to work in close collaboration with the FDA" to complete the approval process. Id. at ¶ 83. Sanofi's shares fell more than 3% after that disclosure. Id. at ¶ 85. Shortly thereafter, the Wall Street Journal published an article about rimonabant, cautioning that the FDA "would approve Sanofi's weight-loss drug only if the company could meet certain conditions." Id. Defendants, however, continued to project that the company would likely receive the FDA's approval for distribution of rimonabant in the United States "within months." Id. at ¶ 19.

Sanofi provided the additional analyses of the clinical data requested by the FDA in the approvable letter. Id. at ¶ 62. However, on June 13, 2007, the final day of the class period, defendants issued a press release stating that the FDA's Endocrinologic and Metabolic Advisory Committee had rejected approval of rimonabant as a treatment for obesity in the United States. Id. at ¶ 36. The value of Sanofi's common stock declined sharply on both the Euronext and the New York Stock Exchange after that announcement. Id. The following day, Sanofi informed investors that it would have to revise its earnings projections to reflect the FDA's decision. Id. at ¶ 38. On June 29, 2007, "Sanofi completely withdrew its NDA for rimonabant" from FDA consideration. Id. at ¶ 39.

PLAINTIFFS' CLAIMS

Plaintiffs allege that defendants' disclosures about rimonabant constituted material misrepresentations because defendants possessed, but failed to disclose, information from the RIO Studies that indicated a relationship between rimonabant and suicidality, knowing that such information would be material to the investing public. Id. at ¶ 76 (alleging that numerous characterizations of rimonabant's safety profile disclosed in conference calls and press releases were misleading because "defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression"); see also id. at ¶¶ 81, 97, 107, 116, 123. Plaintiffs further point to statements made in Sanofi's October 27, 2006 press release filed in connection with the company's Form 6-K as containing material misrepresentations about rimonabant that were reported to investment analysts during a December 5, 2006 conference call. Id. at ¶¶ 109-111.

STANDARD OF REVIEW

Dismissal pursuant to Rule 12(b)(6) is inappropriate "unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief.'" See Blue Tree Hotels Investment, 369 F.3d at 217 (citing Sweet v. Sheahan, 235 F.3d 80, 83 (2d Cir. 2000)). While all reasonable inferences are drawn in the plaintiff's favor, any "conclusions of law or unwarranted deductions of fact are not admitted." See Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 175 (2d Cir. 2005). This Court may consider documents incorporated by reference into a complaint to assess the viability of plaintiffs' claims. See Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322, 127 S. Ct. 2499, 2509 (2007). Although it is generally inappropriate to assess the validity of the allegations on a motion to dismiss, plaintiffs cannot premise their claims

on allegations flatly contradicted by such incorporated documents. See Gant v. Wallingford Bd. of Educ., 69 F.3d 669, 674 (2d. Cir. 1995).

STATING A CLAIM UNDER RULE 10B-5

Section 10(b) of the Securities Exchange Act of 1934 protects investors from corporations which use "manipulative or deceptive device[s] or contrivance" in violation of the securities laws. See Tellabs, 551 U.S. at 318, 127 S. Ct. at 2507. For plaintiffs' Rule 10b-5 claim to withstand defendants' motion, the complaint must contain particularized facts demonstrating that "in connection with the purchase or sale of securities, the defendant, acting with scienter, made a false material representation or omitted to disclose material information and that plaintiff[s'] reliance on defendant's conduct caused plaintiff injury." See Caiola v. Citibank, N.A., N.Y., 295 F.3d 312, 321 (2d Cir. 2002) (internal citation and alterations omitted); Lentell, 396 F.3d at 168 ("Any fraud must be pled with particularity; but the rule is applied assiduously to securities fraud") (citation omitted).

As a threshold matter, the complaint must explain why the allegedly misleading misstatements were fraudulent in order to satisfy the pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. See In re Geopharma, Inc. Sec. Litig., 399 F. Supp.2d 432, 441 (S.D.N.Y. 2005). For such statements to be actionable under Rule 10b-5, the complaint must show that, when read in context and with reference to the total mix of information available to investors, defendants' disclosures were materially misleading. Id.; see also Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 356-57 (2d. Cir. 2002) (Under Rule 10b-5, it is "unlawful for any person to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which

they were made, not misleading) (alternations omitted). Actionable misstatements must be more than simply false; "the other elements of fraud, such as scienter and reliance, must also be present." In re Geopharma, 399 F. Supp.2d at 449.

The essence of plaintiffs' claims is that defendants materially misrepresented the effectiveness of rimonabant to investors and failed to characterize the clinical data in a manner that highlighted the association between rimonabant and suicidality. Complaint at ¶ 76 (alleging that numerous characterizations of rimonabant's safety profile disclosed in conference calls and press releases were misleading because "defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression"); see also id. at ¶¶ 81, 97, 107, 116, 123. In support of that contention, plaintiffs identify scores of alleged mischaracterizations of the RIO Studies defendants made both before and after receiving the FDA's approvable letter. See, e.g., ¶ 32 ("We remain confident and prepared to launch [rimonabant] during the second half of ... 2006"); id. at ¶ 34 (defendants' April 2007 statement, "Rimonabant demonstrated a good safety profile" in the research studies"); id. at ¶ 55 ("We have looked at the [clinical trial] database fairly closely and no concerns have arisen ... We're well along in amassing the entire safety database"). However, at oral argument on defendants' motion to dismiss, plaintiffs rightly conceded that the majority of the allegedly misleading statements identified in the complaint were unactionable statements of opinion or forward-looking statements made within the "safe harbor" provisions of the securities laws. See, e.g., Tr. at 79-81 (discussing defendants' statement "You know everything about rimonabant")[1]; id. at 83-84 (characterization of drug safety data as "very good" not an actionable misstatement); id. at 90-91

[1] Citations to "Tr." refer to the transcript of oral argument before the Court held on March 11, 2009.

(description of study follow up procedures also not actionable). It is well settled that most forward-looking statements, such as predictions about future revenue, accompanied by cautionary language are not actionable under Rule 10b-5. 15 U.S.C. §78u-5(c)(1); see also In re Regeneron Pharmaceuticals, Inc. Sec. Litig., No. 03 Civ. 3111, 2005 WL 225288, at *13 (S.D.N.Y. Feb. 1, 2005) (a statement is entitled to safe harbor protection when it is identified as a forward looking statement and accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement).

Plaintiffs identify three alleged misstatements contained in paragraphs 102, 109, and 110 of the complaint which they believed supported their Rule 10b-5 claim. Tr. at 88-92. In Sanofi's October 27, 2006 press release, defendants allegedly misled investors by stating that the "side effects [of rimonabant] were mainly mild, transient, self-limiting and occurred early in the treatment period." Complaint at ¶ 102. This statement referred to results obtained during Sanofi's study of the use of 20 milligram and 5 milligram dosages of rimonabant in patients with diabetes. Id.[2] Plaintiffs also maintain that during a December 5, 2006 conference call in which defendants disclosed results of another rimonabant trial, defendants misleadingly stated:

> Although there was an increase in the frequency of depressed mood, 5.8% versus 0.7%, in this study we had emphasized the need to evaluate depressed mood and depression in a consistent and rigorous way. And what we actually see, although, there is an increase in the frequency of depressed mood, there is no increase in cases of depression. And, in

[2] The press release went on to note:
"The most frequent side effects included nausea (12.1% for rimonabant 20 mg once daily vs. 5.7% for placebo), dizziness (9.1% for rimonabant 20 mg once daily vs. 4.9% for placebo), diarrhoea (7.4% for rimonabant 20 mg once daily vs. 6.6% for placebo), vomiting (5.9% for rimonabant 20 mg once daily vs. 2.3% for placebo), self-reported hypoglycaemia (5.3% for rimonabant 20 mg once daily vs. 1.7% for placebo), fatigue (5.3% for rimonabant 20 mg once daily vs. 3.7% for placebo) and anxiety (5.0% for rimonabant 20 mg once daily vs. 2.6% for placebo)." Complaint at ¶ 102.

> fact, there is a numerically smaller number of cases of depression in rimonabant 20 milligram indicating that whatever we're seeing in this general area, seems to be mild and, perhaps, more of a tolerability issue than a safety issue. Id. at ¶ 109.

Plaintiffs do not allege that the statistics disclosed during this conference call were incorrect. Rather, they argue that defendants' characterization of the negative side effects of rimonabant as "mild" was inconsistent with the FDA's subsequent conclusion, based on the same data set, that the relationship between the drug and mood disordered was sufficient to prevent approval. For the same reason, plaintiffs contend that defendants' conclusions that the studies' findings with respect to depressed mood were "relatively mild and self-limiting" and that "in the second year there is no difference from placebo" were also materially misleading. Id. at ¶ 110.

In their complaint, plaintiffs argue that "[d]efendants did not disclose to investors or the public the safety data which showed a causal connection between the use of rimonabant and serious side effects such as suicidality and depression." Id. at ¶ 29. However, the three alleged misstatements identified during oral argument and set forth in the complaint fail to support plaintiffs' claims. In fact, plaintiffs' allegations unequivocally demonstrate that accurate rimonabant study data was made available to the public through Sanofi's press releases, S.E.C. filings, and various medical publications. See, e.g., Provenzano Decl., Exs. A-D, G, H, L. The complaint fails to set forth facts showing that defendants misstated the frequency with which negative side effects occurred among the studies' subjects or misrepresented the test patients response to rimonabant vis-a-vis the patients receiving placebos. Thus, taken in context with the publicly available data, defendants' conclusions that the negative side effects were "relatively mild and self-limiting," and their other characterizations, amount to little more than expressions of opinion which are not actionable misstatements under Rule 10b-5. See Nadoff v. Duane

Reade, 107 Fed. Appx. 250, 252 (2d Cir. 2004).

Plaintiffs also base their claims on material omissions which they allege defendants made by unlawfully withholding information about the causal relationship between rimonabant and suicidality from investors. To state a securities fraud claim based on material omissions, plaintiffs must first establish that defendants had "a duty to disclose the omitted information." In re Geopharma, 399 F. Supp.2d at 441. "Omissions are actionable only when they cause the statements actually made to be misleading, or if a duty to disclose is created by statute or regulation." Id. Furthermore, "there is no duty to update vague statements of optimism or expressions of opinion." In re Int'l. Bus. Mach. Corp. Sec. Litig., 163 F.3d 102, 110 (2d Cir. 1998) (citations omitted).

Plaintiffs argue that defendants' failure "to disclose omitted safety data" about rimonabant constitutes a material misrepresentation for Rule 10b-5 purposes. See Pl. Opp. Memo. at 17. Throughout the complaint, however, plaintiffs cite statistics concerning adverse side effects of the drug that were publicly reported as part of the RIO Studies and other clinical trial data. See, e.g., Complaint at ¶ 24 (noting percentage of test patients suffering adverse psychiatric effects who previously had no baseline mood disorders); id. at 26 ("RIO Studies also identified serious safety signals"); id. at ¶ 28 (citing rates of patient withdrawal from the RIO Studies); id. at ¶ 76 ("the RIO Studies ... showed a causal link between rimonabant and suicidal ideation"). Plaintiffs do not allege that Sanofi falsified study data or that defendants concealed clinical data gathered in the trials from either the investing public or the FDA. In fact, plaintiffs have failed to identify any specific safety data that was omitted from Sanofi's public disclosures

which defendants had an affirmative duty to disclose.[3] Compare In re Forest Labs., 2006 WL 5616712, at * 7 (finding material omission where defendants published limited clinical data but concealed "a large, six-year study of [drug's] efficacy and safety" from consumers, financial markets, and company employees). Accordingly, plaintiffs have not identified a material omission sufficient to state a securities fraud claim under Rule 10b-5.

SCIENTER

Even if the complaint had identified actionable misstatements or material omissions, plaintiffs' allegations must also support an inference that such statements were made with *scienter*, an intent "to deceive, manipulate, or defraud, or reckless disregard for the resultant deception." See AUSA Life Ins. Co. v. Ernst and Young, 206 F.3d 202, 207 (2d Cir. 2000). There are two methods by which plaintiffs may successfully allege scienter. They may either allege "facts to show that defendants had both motive and opportunity to commit fraud," or they can allege facts which "constitute strong circumstantial evidence of conscious misbehavior or recklessness." See Chill v. G.E. Co., 101 F.3d 263, 267 (2d Cir. 1996) (internal quotations and citation omitted). With respect to *motive*, plaintiffs must allege that defendants possessed a distinct and concrete incentive to commit securities fraud. See In re Geopharma, 399 F. Supp.2d at 450 ("allegations that a defendant was motivated to commit securities fraud by a desire to reduce its debt burden, or otherwise reduce borrowing costs, are insufficient to raise a scienter inference"); Chill, 101 F.3d at 268 (allegations that defendants' motive was simply "to maintain the appearance of corporate profitability, or of the success of an investment" are insufficiently

[3] Moreover, at oral argument, plaintiffs conceded that defendants did not have an affirmative duty to disclose either the contents of the FDA's approvable letter or Sanofi's response thereto. See Tr. at 86.

particularized to establish scienter). Plaintiffs' allegations must also establish that defendants had an *opportunity* to commit securities fraud which, in this context, requires facts showing that defendants possessed "the means and likely prospect of achieving concrete benefits by the means alleged." Id. at 267 n.4.

Plaintiffs' allegations fail to establish that defendants had both motive and opportunity to commit fraud. In their complaint, plaintiffs allege that defendants "were motivated to conceal the causal connection between rimonabant and suicidal ideation and depression during the Class Period in order to avoid increased scrutiny of outstanding drug applications by regulatory bodies other than the FDA." Complaint at ¶ 63.[4] Plaintiffs also describe Sanofi's "patent woes" during the class period that were symptomatic of drug "pipeline problems" endemic in the pharmaceutical industry at large. Id. at ¶¶ 9-14. Nevertheless, that proffered motive may be ascribed to any pharmaceutical company awaiting approval from multiple authorities. As such, plaintiffs have alleged nothing more than a "generalized motive" insufficient to establish scienter. See Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001) (alleged desire "for the corporation to appear profitable", "to keep stock prices high to increase officer compensation", "or to maintain artificially high prices in order to protect their executive positions and compensation" is insufficient to establish motive).[5] Furthermore, even if the alleged motive were sufficient, the allegations of the complaint make clear that defendants' publicly disseminated the

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[4] It is important to note that plaintiffs have not identified any conclusive finding that rimonabant actually causes suicidality or other mood disorders. See generally In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36, 41 (2d Cir. 2000) ("receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report").

[5] See also Complaint at ¶ 7 ("Sanofi, like other pharmaceutical companies is a research-driven company and its business model depends on the development and regulatory approval of new, patent-protected products to replace other brand-name drugs as they come off patent.").

clinical study data, rendering untenable plaintiffs' claim that defendants had both "motive and opportunity" to withhold material information from the investing public. See, e.g., In re PXRE Grp., Ltd. Sec. Litig., 600 F. Supp.2d 510, 533 (S.D.N.Y. 2009) (finding lack of motive and opportunity where alleged fraudulent scheme was implausible). Thus, the facts set forth in the complaint, even if assumed to be true, fall far short of demonstrating that defendants had both a distinct motive and reasonable opportunity to commit securities fraud.

Plaintiffs also allege that defendants' characterizations of rimonabant's side effects demonstrate recklessness sufficient to prove scienter. It is well settled that plaintiffs bear a "significant burden" in showing recklessness sufficient to state a securities fraud claim. See Chill, 101 F.3d at 270. Their allegations must demonstrate "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. at 269 (citing Rolf v. Blyth, Eastman Sillon & Co., 570 F.2d 38, 47 (2d Cir. 1978)).

Plaintiffs argue that defendants acted recklessly in failing to specifically investigate the relationship between rimonabant and suicidality. See Pl. Opp. Memo. at 22. Plaintiffs also allege, in support of their recklessness theory, that "[i]t is inconceivable that the Individual Defendants did not have knowledge of the safety details of rimonabant" given their access to clinical study data. Id.; see also Tr. 96:5-8 (arguing that defendants' mere access to clinical trial data suggesting a causal relationship supports a strong inference of scienter"). Plaintiffs cannot create an inference of fraud based on recklessness by simply alleging that Sanofi "might have been more cautious or concerned" about negative drug side effects or that they could have

interpreted the clinical trial data in a more conservative fashion. See Chill, 101 F.3d at 270. Defendants repeatedly disclosed instances of adverse side effects which occurred during the trials, and they never guaranteed investors that the drugs were free from all side effects. It was not reckless for defendants to interpret the drug's side effects to be either statistically insignificant or insufficiently severe to prevent FDA approvable. See In re Carter Wallace, 220 F.3d at 41. Even the subsequent denial of FDA approval based on a review of the same available evidence does not support a conclusion of recklessness. Accordingly, the complaint fails to establish scienter under a theory of recklessness.

CLAIMS UNDER § 20(A) OF THE EXCHANGE ACT

Plaintiffs also seek to impose liability on the individual defendants pursuant § 20(a) of the Exchange Act which provides that "controlling persons" may be held jointly and severally liable for a corporation's violations of the securities laws. See Boguslavsky v. Kaplan, 159 F.3d 715, 721 (2d Cir. 1998). To state a viable claim under this provision, plaintiffs must first establish a primary violation of the securities laws. See Ganino, 228 F.3d at 170; see also In re Pfizer, Inc. Sec. Litig., 538 F.Supp.2d 621, 637 (S.D.N.Y. 2008) (Section 20(a) claim must be dismissed against individual defendants if plaintiffs fail to state a claim for a primary violation of Section 10(b) of the Exchange Act). Thus, because plaintiffs have failed to state a *prima facie* violation under Rule 10b-5, their claims against the Individual Defendants must also be dismissed.

CONCLUSION

Defendants' motion to dismiss is granted. Plaintiff's claims are dismissed.

Dated: September 25, 2009
New York, New York

George B. Daniels

GEORGE B. DANIELS
United States District Judge