NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION	:	**MDL No. 1658 (SRC)**
	:	**Civil Action No. 05-1151 (SRC)**
	:	**Civil Action No. 05-2367 (SRC)**
THIS DOCUMENT RELATES TO: THE CONSOLIDATED SECURITIES ACTION	:	**OPINION**

CHESLER, District Judge

Lead Plaintiffs bring this motion for leave to file a Sixth Amended Class Action Complaint ("Sixth Amended Complaint"). The amendments they propose fall into two categories: (1) allegations relating to a November 1, 2004 Wall Street Journal article and the effect of the information contained therein had on the value of Merck stock and (2) allegations regarding alleged misstatements about a high-risk group's participation in the VIGOR study and its effects on the study's results. Defendants Merck & Co., Inc. and Alise Reicin (collectively, "Defendants" or "Merck") have opposed the motion. The Court has considered the papers filed by the parties and, for the reasons that follow, will grant the motion in part and deny it in part.

I. BACKGROUND

In its August 8, 2011 Opinion addressing Defendants' motion to dismiss the Corrected Consolidated Fifth Amended Class Action Complaint ("Fifth Amended Complaint"), the Court found that the November 1, 2004 Wall Street Journal article did not constitute a corrective disclosure and dismissed Plaintiffs' Rule 10b-5 claim to the extent it was based on that article's contribution to a drop in value of Merck shares for lack of loss causation. In particular, the Court held that the allegations relating to the November 1, 2004 article failed to state the essential element of loss causation because on September 30, 2004, upon Merck's withdrawal of Vioxx from the market because of an increased risk of confirmed cardiovascular events associated with Vioxx use, the fraud on which this lawsuit is based was revealed to the public. The Court reasoned that the false valuation of Merck stock based on the subject misrepresentations and omissions about Vioxx was removed by the September 30, 2004 disclosure, which made clear that Vioxx was no longer a commercially viable product.

In the instant motion, Plaintiffs seek to re-introduce the November 1, 2004 Wall Street Journal article as a curative disclosure, arguing that it was not until the revelation of information contained in that article that the market became fully aware of the extent of Vioxx-related liability exposure faced by Merck. As the August 8, 2011 Opinion summarized, the November 1, 2004 Wall Street Journal piece described previously undisclosed internal Merck documents which demonstrated that Merck was aware of Vioxx's link to a greater incidence of adverse cardiovascular events. According to Plaintiffs, Merck's misrepresentations and omissions not only overstated the commercial viability of Vioxx but also understated the liabilities associated with Vioxx's safety problems, and the latter aspect of the fraud's effect on the overvaluation of Merck stock could not be internalized by the market until the November 1, 2004 article reported

various facts concerning Merck's suppression of critical information. Plaintiffs allege that "[t]he November 1, 2004 Wall Street Journal article significantly increased the market's view of Merck's VIOXX-related litigation exposure, including potential punitive damage awards." (Sixth Am. Compl., ¶ 313.)

Plaintiffs indicate that, unlike the previous pleading found insufficient by the Court to state loss causation, the proposed Sixth Amended Complaint alleges additional facts that support the causal link between the subject securities fraud and the November 1, 2004 drop in Merck's stock price. The proposed amended pleading alleges that on September 30, 2004 and in the days shortly following Vioxx's withdrawal, analysts "recognized the significant VIOXX liability exposure that Merck faced," (Id., at ¶ 314) but generally found it too early to quantify that risk with precision. At best, estimates made by analysts prior to the November 1, 2004 article put the exposure in the range of hundreds of millions of dollars to approximately $10 billion. (Id.) According to Plaintiffs, the impact of the article's new information about Merck's allegedly deliberate misrepresentations and omission of material fact concerning Vioxx's safety risks was as follows:

> As analysts and the press recognized, however, publication of the November 1, 2004 Wall Street Journal article (because of its exposure for the first time of the magnitude of Merck's efforts to hide the adverse information about the cardiovascular risks of VIOXX and Merck's long-held knowledge about those risks) changed the market's view and significantly increased Merck's expected exposure to VIOXX-related litigation, including Merck's exposure to punitive damages awards, and led several Wall Street analysts to report significantly higher estimates of Merck's liability exposure in contrast to the pre-November 1, 2004 timeframe. The concerns over Merck's litigation exposure also led to noteworthy analyst downgrades as well as a "CreditWatch" announcement by Standard & Poor's. While Merck previously had removed VIOXX from the market and reduced the drug's near-term commercial viability to nearly zero (barring a potential return of VIOXX to the market), the disclosures in the November 1, 2004 Wall Street Journal article

> significantly increased the market's estimates of potential costs to Merck to resolve VIOXX litigation, which was a foreseeable consequence of Defendants' fraud, as well as the materialization of the concealed risks concerning Merck's exposure to VIOXX liability. The additional facts revealed in the November 1, 2004 Wall Street Journal article further corrected Defendants' misstatements regarding VIOXX's true safety risks and proximately caused investors to suffer additional losses as the market increased its estimates for Merck's VIOXX-related liability.

(Id., ¶ 315.)

The other category of proposed amendments concerns allegations that Defendants falsely stated that the inclusion of a high-risk subgroup of patients in the VIGOR trial supported Merck's claims that the results of the trial were attributable to naproxen's purported cardioprotective effect (as opposed to Vioxx's propensity to increase the risk of a negative cardiovascular event, or prothrombotic effect). In particular, Plaintiffs seek to add factual allegations that Defendants deceived investors regarding the safety profile of Vioxx by explaining that four percent of the participants in the VIGOR trial should have been receiving prophylactic aspirin therapy to prevent heart attacks and strokes and insinuating that these were the VIOXX-taking participants who suffered the majority of the heart attacks. (For simplicity, the Court will refer to this alleged misrepresentation as the "4% Statement.") According to the proposed Sixth Amended Complaint, Merck misled investors with an analysis suggesting that the VIGOR results (which indicated a higher incidence of heart attack in patients taking Vioxx than those taking naproxen) were driven by the high-risk subgroup of patients who should have been screened out in accordance with the study's protocol. (Id.,¶ 125.) In particular, the VIGOR trial was supposed to exclude any patients presenting a high risk for cardiovascular events and indicated for low-dose aspirin prophylaxis. (Id., ¶ 126.) Plaintiffs allege that the 4% Statement was materially misleading because it communicated to the public that this supposedly higher-risk

aspirin-indicated subgroup faced a qualitatively different cardiovascular risk than the rest of the VIGOR population, and the incidence of adverse cardiovascular events within that subgroup was quantitatively different in a meaningful and demonstrable way. In this way, according to Plaintiffs, Merck bolstered its claim that the results observed in VIGOR were entirely consistent with the naproxen hypothesis. (Id., ¶ 127.) The proposed Sixth Amended Complaint avers that the 4% Statement was made in a May 24, 2000 press release by Merck and in a November 23, 2000 article in the New England Journal of Medicine, which listed, among others, Defendant Reicin and Merck statistician Deborah Shapiro as authors. (Id., ¶ 125.)

II. DISCUSSION

A. Legal Standard

Rule 15(a) of the Federal Rules of Civil Procedure governs motions for leave to amend a complaint. While Federal Rule of Civil Procedure 15(a) directs that leave to amend a complaint should be freely given, the Supreme Court has held that leave to amend should be denied based, among other reasons, for undue delay, bad faith, undue prejudice, and futility of the proposed amendment. Foman v. Davis, 371 U.S. 178 (1962). Merck takes the position that the instant motion should be denied in its entirety because expanding the Exchange Act claims in the two ways proposed by Plaintiffs – to include allegations regarding the November 1, 2004 Wall Street Journal article and allegations regarding the 4% Statement – would be futile. When assessing the futility of a proposed amendment, the Court applies the same analysis it would in a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997).

To state a claim that survives a Rule 12(b)(6) motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and then determine whether a reasonable inference may be drawn that the defendant is liable for the alleged misconduct." Argueta v. U.S. Immigration and Customs Enforcement, 643 F.3d 60, 74 (3d Cir. 2011)

B. Allegations Regarding the November 1, 2004 Wall Street Journal Article

Merck argues that it would be futile to expand the § 10(b) claim to include the market's reaction to the November 1, 2004 Wall Street Journal article because it lacks the required correlation to the alleged fraud, that is, a disclosure which could plausibly establish a causal connection between the fraud and the November 1, 2004 stock price drop. To reiterate from the Court's previous opinion in this case, a § 10(b) claim includes a loss causation element. 15 U.S.C. § 78u-4(b)(4); Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 342 (2005). To establish loss causation, a plaintiff must "show that a misrepresentation that affected the integrity of the market price also caused a subsequent economic loss." Erica P. John Fund, Inc. v. Halliburton, 131 S.Ct. 2179, 2186 (2011); see also McCabe v. Ernst & Young, LLP, 494 F.3d 418, 426 (3d Cir. 2007) ("In order to satisfy the loss causation requirement . . . the plaintiff must show that the defendant misrepresented or omitted the very facts that were a substantial factor in causing the plaintiff's economic loss"). Pleading the requisite causal connection between investment loss and the alleged fraud requires a § 10(b) plaintiff to allege "that the misstatement or omission

concealed something from the market that, when disclosed, negatively affected the value of the security." Lentell v. Merrill Lynch, 396 F.3d 161, 173 (2d Cir. 2005).

The November 1, 2004 Wall Street Journal article did not, however, disclose any previously unknown information that revealed the falsity of Merck's statements and omissions regarding the cardiovascular safety profile of Vioxx. That alleged fraud – which forms the basis of the § 10(b) securities fraud claim pled in this action – was exposed at the time that Vioxx was withdrawn from the market by Merck based on concerns with its possible propensity to increase the risk of heart attack or stroke. In contrast, the information reported in the November 1, 2004 Wall Street Journal, which included internal Merck communications indicating awareness of Vioxx's possible cardiovascular risks long before the market withdrawal, prompted analysts to make revised estimates of the damages that may flow from Vioxx-related lawsuits. As the Court held in its August 8, 2011 Opinion, the facts regarding Merck's awareness of Vioxx's safety issues relate to Merck's state of mind in making the alleged misrepresentations and omissions, but that disclosure did not correct or reveal a previously unknown deception. Now, Plaintiffs argue that the corrective disclosure of the November 1, 2004 Wall Street Journal article consists of the revelation that, in light of the deliberate and intentional nature of Merck's deception regarding Vioxx's safety profile, Merck's liability exposure was much greater than previously thought, according to third-party financial and market analysis of the information regarding Merck's knowledge. Such analysis of facts probative of Merck's scienter may be "bad news," which in turn appears to have precipitated a 9.7% drop in the price of Merck stock, but it is not congruent with the fraud alleged in this case and therefore fails to support loss causation. McCabe, 494 F.3d at 426; Lentell, 396 F.3d at 175 and n.4 (holding that, although stock price dropped upon a downgrade of the stock, such downgrade did not amount to a corrective

disclosure because it did not reveal to the market the falsity of the prior recommendations by the defendant to buy or accumulate the stock); In re Tellium, Inc. Sec. Litig., No. 02CV5878 (FLW), 2005 WL 2090254, at *4 (D.N.J. Aug. 26, 2005) (holding that "an announcement of bad news that does not disclose the fraud" does not plead loss causation as required to state a § 10(b) claim). Just as the underlying state of mind information reported in the November 1, 2004 Wall Street Journal article did not make Defendants' alleged fraud known to the public, interpretation by analysts of that information did not disclose the fraud on which Plaintiffs ground their § 10(b) claim and could not, therefore, "correct" that fraud's artificial inflation of Merck stock. This lawsuit is not premised on allegations that Merck misrepresented or concealed from investors material facts concerning Merck's exposure to liability stemming from products liability suits and consumer fraud claims related to the alleged cardiovascular risks of Vioxx. Indeed, the public knew of such lawsuits being filed against Merck as early as May 29, 2001, yet as Plaintiffs themselves have maintained, the fraud giving rise to their § 10(b) claim is distinct from the negative Vioxx information disclosed to the public by virtue of those lawsuits.

In spite of Plaintiffs' arguments that due to the November 1, 2004 Wall Street Journal article, the market finally became fully aware of the losses the company could face as a result of Vioxx litigation and reacted accordingly, the Court concludes that Plaintiffs have failed to demonstrate that the information publicized in that article concerned the very facts Plaintiffs allege were misrepresented and/or omitted by Merck. They have not pled a causal connection between the November 1, 2004 drop in stock price and the fraud at issue. As the loss causation element of the § 10(b) claim fails to meet the plausibility standard of Rule 8(a), amendment of the claim to include the allegations relating to the November 1, 2004 Wall Street Journal article

and its effect on the price of Merck stock would be futile. Leave to file an amended complaint to add these allegations will be denied.[1]

C. Allegations Regarding the 4% Statement

The 4% Statement appeared in two publications. According to the proposed Sixth Amended Complaint, it was first made in a Merck press release dated May 24, 2000 and then repeated, in essence, in a November 23, 2000 article in the New England Journal of Medicine concerning the VIGOR study. Merck argues that as to both publications of the 4% Statement, leave to amend must be denied because the statement was not false or misleading and thus fails to support a § 10(b) claim. It points out that the proposed Sixth Amended Complaint does not quote the actual text of May 24, 2000 press release, in which the 4% Statement, as characterized by Plaintiffs, first appeared. That press release stated, in relevant part, as follows:

> In VIGOR, there was no difference in cardiovascular mortality and the incidence of strokes between the groups treated with Vioxx or naproxen. As previously reported, significantly fewer heart attacks were seen in patients taking naproxen (0.1 percent) compared to the group taking Vioxx (0.4 percent) in this study. [footnote omitted]
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> The reduction in heart attacks is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1. This effect on platelet aggregation is similar to low-dose aspirin, which is used to prevent second cardiac events in patients with a history of heart attack, stroke or other cardiac events. Patients taking low-dose aspirin did not participate in VIGOR although 4 percent of patients enrolled in the study did meet the criteria for use of aspirin to prevent second cardiac events. Among the 96 percent of patients in VIGOR who were not candidates for low-dose aspirin for such cardioprotection, there was no significant difference in

[1] Relatedly, the Court rejects Plaintiffs' effort to revive as actionable Gilmartin's September 30, 2004 statements, made following market withdrawal of Vioxx. Plaintiffs argued in their motion that, because the fraud was not fully known until November 1, 2004, Gilmartin's September 30, 2004 statements "have a whole new meaning in light of the liability-side analysis Plaintiffs now present." (Reply Br. at 15.) In light of the foregoing discussion, the Court's holding that Gilmartin's September 30, 2004 statements were immaterial remains the law of this case. See In re Merck & Co., Inc. Securities, Derivative & ERISA Litig., No. 05-1151, 2011 WL 3444199, at *17-18 (D.N.J. Aug. 8, 2011).

> heart-attack rates – 0.1 percent among patients taking naproxen and 0.2 percent among patients taking Vioxx.

(DeMasi Decl., Ex. 17 at 2.)[2] Similarly, the New England Journal of Medicine article stated:

> Four percent of the [VIGOR] study subjects met the criteria of the Food and Drug Administration (FDA) for the use of aspirin for secondary cardiovascular prophylaxis . . . but were not taking low-dose aspirin therapy. These patients accounted for 38% of the patients in the study who had myocardial infarctions. In the other patients the difference in the rate of myocardial infarction between groups was not significant (0.2 percent in the rofecoxib [Vioxx] group and 0.1 percent in the naproxen group).

(Id., Ex. 19 at 1523.) Merck further argues that insofar as the 4% Statement appeared in the New England Journal of Medicine article, the proposed additional allegations would be futile for the additional reason that Plaintiffs fail to allege that either Merck or Dr. Reicin "made" the allegedly offending statement, in compliance with the Supreme Court's holding in Janus Capital Group, Inc. v. First Derivative Traders, 131 S.Ct. 2296, 2302 (2011).

The Court is not persuaded by either of Merck's futility arguments as to the allegations regarding the 4% Statement.

First, as Plaintiffs argue without conceding, even if the 4% Statement made in the press release was partially or technically accurate, the proposed Sixth Amended Complaint alleges that in making this assertion about the aspirin-indicated subgroup, Merck omitted to state that the risk of adverse cardiovascular event observed in the subgroup was not statistically different from the risk in the remainder of the VIGOR population. Securities law requires that once a defendant speaks about a particular subject, it must not omit material information required to convey

[2] Pursuant well-established law concerning materials the Court may consider upon review of the sufficiency of a complaint, the press release, while not quoted in the proposed Sixth Amended Complaint, may be considered as an undisputedly authentic document expressly referenced and relied upon by the pleading. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007); Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). The same holds true for the Court's consideration of the text of the New England Journal of Medicine article.

accurate and complete information to investors on that subject. Merck, 2011 WL 3444199, at *9. Assuming the facts alleged to be true, the proposed Sixth Amended Complaint plausibly states that investors were misled to believe that the 4% subgroup was responsible for the higher incidence of heart attack and stroke in the Vioxx-arm of the study.

Second, regarding what it means to make a statement in the securities fraud context, the Supreme Court held in Janus that "[f]or purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement including its content and whether and how to communicate it." Id. at 2302. In contrast, "[o]ne who prepares or publishes a statement on behalf of another is not its maker." Id. The New England Journal of Medicine article was in fact co-authored by Merck employees, including Defendant Reicin, as well as non-Merck employees. Moreover, by the time the article was published, on November 23, 2000, Merck had already explicitly disseminated its 4% Statement through the May 24, 2000 press release. The article reiterates Merck's analysis concerning the aspirin-indicated subgroup's participation in the VIGOR study. Reading the allegations as a whole and with consideration of the context and circumstances surrounding publication of the article, the proposed Sixth Amended Complaint sufficiently alleges that Defendants made the 4% Statement in the New England Journal of Medicine article. See id. (holding that "attribution within a statement or implicit from surrounding circumstances is strong evidence that a statement was made by – and only by – the party to whom it is attributed."). Defendants argue that publication of the article following peer review as well as collaboration by various authors, including individuals not affiliated with Merck, negates attribution of the 4% Statement to Merck and/or Reicin because these facts indicate that Defendants did not control the statement. Janus, in holding that explicit or implicit attribution of a statement to a party – both of which are alleged in this case as to Defendants –

demonstrates that the party made the statement, would appear to undercut Defendants' argument. The article containing the 4% Statement was not prepared or published *on behalf of* Defendants; Merck and Reicin, as authors, had authority over it, assuming the facts alleged in the proposed Sixth Amended Complaint to be true.

In short, the Court concludes that amendment of the Complaint to add allegations concerning the 4% Statement satisfies the standard of Rule 15. As alleged, the 4% Statement, read in context, bolsters the naproxen hypothesis (Merck's explanation of the VIGOR results as attributable to the cardioprotective qualities of naproxen as opposed to the prothrombotic effect of Vioxx) and thus relates to the core of Plaintiffs' § 10(b) claim. For the reasons stated, the Court finds that Plaintiffs have sufficiently alleged that the 4% Statement is actionable under § 10(b) and Rule 10b-5.

III. CONCLUSION

The Court will deny the motion for leave to amend insofar as it concerns expanding the § 10(b) claim to include the November 1, 2004 Wall Street Journal article and contemporaneous drop in Merck stock price, as such an amendment would be futile for lack of loss causation to support the claim. It will permit Plaintiffs to file a Sixth Amended Complaint which adds allegations concerning the 4% Statement, as discussed above.

The Sixth Amended Complaint, moreover, must conform to all prior rulings in this case identifying which alleged misstatements and/or omissions the Court has held do not give rise to a claim under Rule 10b-5. While the binding effect of the Court's orders dismissing certain statements as inactionable may seem obvious, the Court must make this point explicit in light of Merck's indication that the proposed Sixth Amended Complaint contains allegations which

reassert statements that the Court addressed in its August 29, 2012 Opinion on Merck's motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) and that it held insufficient to state a claim. The August 29, 2012 Opinion expressly listed paragraphs, per the numbering of the Fifth Amended Complaint, which failed to state a claim upon which relief could be granted. The Sixth Amended Complaint may not revive claims by repeating portions of previously dismissed factual allegations that Plaintiffs believe continue to remain viable.

An appropriate order will be filed.

s/Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: May 29, 2013