NOT FOR PUBLICATION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

Defendants Merck & Co., Inc. ("Merck") and Alise S. Reicin ("Reicin") have moved for summary judgment pursuant to Federal Rule of Civil Procedure 56(a). Defendant Edward Scolnick ("Scolnick") has joined in their arguments and has also filed his own motion for summary judgment. Plaintiffs have opposed the motions. The Court has considered the papers filed by the parties and proceeds to rule without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons that follow, the Court will grant Merck's motion in part and deny it in part. Scolnick's motion will also be granted in part and denied in part.

I. INTRODUCTION

This securities fraud action arises out of alleged misrepresentations and omissions concerning the Merck pharmaceutical product known as Vioxx, commercially launched in May

1999 and removed from the market on September 30, 2004. The background of this case is well-known to the parties and have been repeatedly summarized in the many opinions the Court has issued. As such, the factual synopsis included in this Opinion will strive to provide an overview of the relevant timeline as well as highlight some important events without expanding into a comprehensive review of all the evidence presented by the parties in connection with this motion. This approach, however, should not give the impression that the record is concise. Rather, it is dense and extensive, spanning many years from the time of Merck's pre-market development of the drug to the time Vioxx was withdrawn from the market.

The procedural history of this litigation, initiated in 2004 and assigned to this Court by the Judicial Panel on Multidistrict Litigation in 2005, is likewise extensive. At this stage, the parties come before the Court after Plaintiffs' successful motion for class certification. By Order of January 30, 2013, the Court certified, pursuant to Federal Rule of Civil Procedure 23(b)(3), a class consisting of "all persons and entities who, from May 21, 1999 to September 29, 2004, inclusive (the "Class Period"), purchased or otherwise acquired Merck & Co., Inc. ("Merck") common stock or call options, or sold Merck put options (the "Class")." The Class is represented by the Public Employees' Retirement System of Mississippi ("MPERS"), Steven Le Van, Jerome Haber and Richard Reynolds (collectively, the representatives and the Class will be referred to as "Plaintiffs.") The active claims in this case are as follows: (1) violation of Section 10(b) of the Securities Exchange Act of 1934 ("the Exchange Act"), against Defendants Merck, Reicin and Scolnick; (2) violation of Section 20(a) of the Exchange Act against Defendants Reicin and Scolnick; and (3) violation of Section 20A of the Exchange Act against Scolnick.

At the expense of making a redundant point, the Court emphasizes that this is a *securities fraud* action. The claims asserted are aimed at holding Defendants accountable for making

statements and withholding information about Vioxx's cardiovascular risk, through which Defendants allegedly misled investors with a wrongful state of mind. While the parameters of the action may appear to be obvious, the arguments presented to the Court on this summary judgment motion reveal that the parties, to some extent, misapprehend the nature of the alleged wrongdoing. This lawsuit is not about whether Vioxx was a fine medication that met an important therapeutic need, as Defendants have maintained, or a product whose great risk to cardiovascular health was disregarded by Merck in pursuit of profit, as Plaintiffs presentation implies. Nor is it about Merck's conduct in testing and studying Vioxx, both before and after its market introduction. The question at issue is not whether these activities met the appropriate standard of care or performance. The Court feels compelled to draw these boundaries at the outset of this Opinion because the papers submitted to the Court more than occasionally blur the focus of the securities fraud claims. This action is solely about whether Defendants spoke publicly about Vioxx in a way that intentionally or recklessly defrauded investors in Merck. The Court's analysis of the claims pursuant to the summary judgment standard will be guided accordingly.

II. FACTUAL SUMMARY

A. Vioxx and Selective Cox-2 Inhibition

Vioxx, the brand name for generic drug rofecoxib, belongs to a class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). NSAIDs are commonly used to treat the symptoms of arthritis. Vioxx was developed by Merck in the 1990s with the aim of creating an NSAID that would relieve pain without causing the gastrointestinal complications associated with traditional NSAIDs, such as aspirin and ibuprofen. The mechanism through

which Vioxx achieved this result is an important piece of the background information in this action and thus warrants some explanation.

In general, NSAIDs work by inhibiting the cyclooxygenase ("Cox") enzyme, which is involved in the production of chemicals in the body called prostaglandins. Prostaglandins promote pain and inflammation, but they also protect the stomach lining and have an anti-coagulation effect on platelets. In the early 1990s, scientists discovered that the Cox enzyme exists in two isoforms, Cox-1 and Cox-2. Cox-1 is responsible for prostaglandin synthesis, a function that protects the gastrointestinal ("GI") tract, whereas Cox-2 is responsible for the actual production of prostaglandins. Traditional NSAIDs inhibit both isoforms, thereby reducing inflammation but also increasing the risk of adverse GI effects. In contrast, Vioxx selectively inhibits only Cox-2, thus suppressing prostaglandin production and reducing pain and inflammation without inhibiting the protective GI function of Cox-1.

B. Pre-FDA Approval: Protocol 023 and the FitzGerald Hypothesis

Merck conducted 60 clinical trials of Vioxx before the drug was approved for marketing by the Food and Drug Administration ("FDA"). One of these was Protocol 023, undertaken to study the renal effects of Vioxx. It was led by Merck consultant Dr. Garret FitzGerald, Professor of Medicine and Pharmacology at the University of Pennsylvania and a world-renowned expert in prostaglandins. To examine the effects of Vioxx on the kidney, Protocol 023 measured the excretion of various urinary metabolites in older adults, with the recognition that older adults are prone to disorders such as diabetes but also comprise a large portion of the population that stands to benefit from the relief of arthritis symptoms offered by NSAIDs. Participants in the study were given daily doses of 50 mg of Vioxx, 50 mg of indomethacin (a traditional NSAID, i.e., Cox-1/Cox-2 inhibitor) and placebo. The investigators were focused on sodium excretion, but

they also measured urinary excretion of prostacyclin metabolites and thromboxane metabolites, both indicators of the body's metabolism of prostaglandins. Prostacyclin is a prostaglandin which inhibits platelet aggregation (blood clotting) and dilates blood vessels, whereas thromboxane is a substance that promotes platelet aggregation. The final results of the two-week Protocol 023 trial revealed that the patients receiving Vioxx showed decreased levels of prostacyclin metabolites but not thromboxane metabolites. On October 20, 1997, Dr. Briggs Morrison, the Executive Director of Worldwide Clinical Data Management at Merck during the Class Period, sent a memo to various Merck employees, including Defendants Scolnick and Reicin, informing them of the final data from Protocol 023. He highlighted the observed effect of Vioxx on the imbalance in prostaglandin metabolites, calling it the "most surprising result from this study" and noting that it would be discussed with prostaglandin experts. (DeMasi Decl., Ex. 30.)

Among those commenting on the Protocol 023 results was Dr. FitzGerald himself. His interpretation of the data came to be known as the "FitzGerald Hypothesis." He posited that the mechanism of selective COX-2 inhibitors, such as Vioxx, which suppresses prostacyclin (anti-clotting function) without supressing thromboxane (clotting function) "might mediate a risk of thrombosis from COX-2 inhibitors in predisposed individuals." (De Masi Decl., Ex. 31 at 714-15.) The concern was that thrombosis could lead to adverse cardiovascular events, such as myocardial infarction (heart attack). Regarding his hypothesis, Dr. FitzGerald testified at his deposition as follows:

> We had evidence for mechanism. The question was did the mechanism have a consequence. And it wasn't whether some people were getting Vioxx that shouldn't be. It was really, you know, does this mechanism actually result in a clinical consequence. And in the absence of data from a placebo-controlled trial, it was conjecture and open to interpretation.

(DeMasi Decl., Ex. 27: FitzGerald Dep. at 198:23-199:17.)

In or about late 1997, the initial draft of the abstract for the Protocol 023 paper was reviewed by Merck. The paper itself, however, was not submitted for publication for many months, apparently due to a prolonged editing process. Dr. FitzGerald, who prepared the manuscript together with Dr. Francesca Catella-Lawson, a University of Pennsylvania colleague who also worked on Protocol 023, disagreed with many of the edits Merck proposed. The main disagreement appears to have been over the conclusions that could be drawn from the data with regard to the role of Cox-2 in the body's biosynthesis of prostacyclin, the chemical which inhibits clotting. In the end, the Protocol 023 paper reported that the 50 mg dose of Vioxx had "no effect on Cox-1 dependent thromboxane biosynthesis" but that the specific Cox-2 inhibition did result in "partial suppression of both renal and extrarenal biosynthesis of prostacyclin." (DeMasi Decl., Ex. 26 at 853.) It concluded that "[t]he implications of prostacyclin suppression in vivo are unclear." (Id. at 854.) The Protocol 023 paper was published in The Journal of Pharmacology and Experimental Therapeutics in May 1999.

In the meantime, and well before the Protocol 023 paper was finalized, Merck undertook a study in 1997 to address the "concern about the potential for Vioxx to predispose to cardiovascular (CVD) thrombotic events."[1] (Graziano Decl., Ex. 93 at MRK-SHAA0653246-47.) The study was initiated at the direction Scolnick, who asked Merck's epidemiology department to evaluate the incidence of CV events observed in the Vioxx trials. Dr. Douglas Watson was assigned to conduct the analysis. The "Watson Analysis," as this study came to be known, aimed to determine whether the number of CV events reported in the Vioxx osteoarthritis trials—many of which were ongoing and still blinded (meaning it was not disclosed whether a patient in the trial was receiving Vioxx, a comparator NSAID or placebo)—was within an expected range. To do this, Dr. Watson compared the aggregate data on CV events in the Vioxx trials to the data from the placebo-only patients in the large-scale and completed studies of two other Merck drugs, Fosamax and Proscar.[2] In his February 2, 1998 report of the analysis he conducted (the "Watson Report"), Dr. Watson stated that, overall, the CV event incidence rates in the Vioxx trials "appear to be roughly consistent with what would be expected in the general population, and there is no clear evidence of consistently elevated adjusted risk compared to placebo controls from PROSCAR and FOSAMAX trials." (DeMasi Decl., Ex. 43: Watson Report at 321.) He did note an elevated risk for one segment, reporting

[1] Merck has noted that Plaintiffs make use of this statement out of context to assert that Dr. Watson wrote that Protocol 023 "raised concern about Vioxx's potential to predispose to CV thrombotic events." The full statement, Merck points out, recognizes that the "clinical implications of [Protocol 023] are unknown" and further makes clear that, despite this concern, "there has not been any evidence of an increased incidence of such [CV] events in clinical trials of Vioxx to date." (Graziano Decl., Ex. 93 at 246-47.)

[2] The study on Fosamax, an osteoporosis drug, provided data on CV events in women, and the study on Proscar, which treats enlarged prostate, provided data regarding men.

that the incidence rate for women in the Vioxx trials (that is, patients receiving Vioxx, an NSAID comparator or placebo) was over twice that of the Fosamax placebo controls, a statistically significant result. Dr. Watson, however, expressed that the increased risk for women in the Vioxx group was not of concern because, in his view, it was driven by atypically low rates of CV events in some of the Fosamax placebo population. The Watson Report concluded that "no change in the conduct of the VIOXX trials appears warranted based on present results. An analysis of CV SAE [serious adverse event] event rates in patients treated with VIOXX compared to those treated with VIOXX placebo/comparators is recommended when the trial databases are unblinded." (Id. at 336.)

Protocol 023 was also on the agenda of a May 1998 meeting Merck had with its Board of Scientific Advisors ("BSA"). The BSA was, at the time, comprised of 27 non-Merck scientists and physicians with expertise in various areas, including cardiology, pharmacology and biostatistics. Its chair, Dr. John Oates, was an expert in prostaglandins. Indeed, Dr. Oates had been consulted by Merck soon after it learned the results of Protocol 023, for his opinion on the likely source of the prostacyclin metabolites. Dr. Oates advised Merck that studies indicated that the major source of prostacyclin was in vasculature and other areas outside the kidneys, making it unlikely that the observed metabolite imbalance indicated a renal issue.

At the May 1998 meeting, Merck presented the Protocol 023 results to the BSA. The BSA recognized that the data was "important," but "not the basis for any conclusion." (DeMasi Decl. Ex. 44 at 13.) According to the BSA, "it should be taken as the basis for hypotheses that should be actively pursued." (Id.) In this regard, the BSA expressly noted two hypotheses: that the data does not implicate systemic or vascular functions or that it does. The latter essentially expressed the same idea as the FitzGerald Hypothesis linking Vioxx's selective inhibition of

Cox-2 to an increase in the risk of adverse CV event. The BSA recommended that Merck actively pursue additional data regarding the source of prostacyclin metabolite and that Merck implement a formal plan to collect and analyze CV data from ongoing Vioxx clinical trials. From this meeting, the BSA concluded as follows:

> The above considerations regarding hypothetical adverse effects and potential unexpected therapeutic benefits of Vioxx are part of the scientific intelligence gathering appropriate to the development of any truly novel pharmacological entity, and should be addressed in parallel with the conclusion of the process of acquisition and analysis of the data that will place this drug in the hands of patients. The gain in safety achieved by the elimination of serious and fatal gastrointestinal toxicity will free patients from one of the most serious adverse effects in current drug therapy. Thus, there is a strong mandate for introduction of Vioxx into medical practice as soon as is feasible.

(Id. at 17.)

Merck took additional actions in response to the Protocol 023 data. It formed a task force for "Cardiovascular SAE surveillance." This group acknowledged that the clinical implications of the data, in particular regarding the possibility for increased risk of thrombotic CV event, remained unknown. In addition, Merck consulted with its various outside experts, including Drs. FitzGerald and Oates, who recommended that further studies of the data be performed. Plaintiffs point out that Merck did not follow this recommendation.

C. FDA Approval of Vioxx

Merck submitted the Vioxx New Drug Application ("NDA") to the FDA on November 23, 1998. It sought approval to market the tablet and oral formulations of the drug for the treatment of the symptoms of osteoarthritis, the relief of acute pain and the symptoms of primary dysmenorrhea. As updated, the NDA for Vioxx included data from 60 clinical trials (including Protocol 023) involving 10,000 individuals, over 5,400 of whom were treated with Vioxx. The

NDA also included in its Clinical Safety Section an unblinded analysis of thrombotic CV events in the clinical database, which concluded that Vioxx groups "have a similar incidence of thromboembolic cardiovascular adverse experiences compared with placebo and NSAID comparators." (DeMasi Decl., Ex. 14 at 1254.)

On May 20, 1999, the FDA approved Vioxx for "relief of the signs and symptoms of osteoarthritis, management of acute pain [in adults] and treatment of primary dysmenorrhea."[3] (Graziano Decl., Ex. 65 at 1.) On May 21, 1999, Merck issued a press release announcing FDA approval of the drug and listing the "most common side effects reported in clinical trials with Vioxx" as "upper-respiratory infection, diarrhea and nausea." (Id., Ex. 66 at 2.)

D. VIGOR

At the time Vioxx was approved by the FDA, a large-scale, double-blind clinical trial of the drug had been underway to study gastrointestinal outcomes in patients with rheumatoid arthritis. This study, known as VIGOR (Vioxx Gastrointestinal Outcomes Research), sought to examine whether Vioxx significantly reduced the risk of serious GI complications (i.e., stomach perforations, ulcers and bleeds, or "PUBs") as compared to the traditional NSAID naproxen. The study enrolled 8,076 rheumatoid arthritis patients, randomly assigning roughly half of them to receive a 50 mg daily dose of Vioxx and the other half to receive 500 mg of naproxen twice daily.

On March 9, 2000, the results of the VIGOR study were unblinded to a group of Merck scientists, including Reicin and Scolnick. While VIGOR confirmed Vioxx's GI benefit versus

[3] Later in the period of time at issue in this lawsuit, the FDA would approve Vioxx for other indications: rheumatoid arthritis (April 2002), migraine (March 2004) and juvenile rheumatoid arthritis (August 2004).

naproxen, the data also showed a statistically significant difference in CV events in the Vioxx arm versus the naproxen arm. In particular, the Vioxx group experienced a five-fold greater number of myocardial infarctions than the naproxen group.

Merck does not dispute that, internally, the initial assessment of the data was that the greater number of CV events in the Vioxx arm was attributable to a prothrombotic effect of Vioxx. At his deposition, Scolnick testified that his "very first reaction was that Vioxx had elevated the rate as opposed to naproxen lowering the rate, and my connection was to the prostacyclin hypothesis, which was my set of first thoughts when I saw the data. That's what I was talking about, since COX-2 inhibitors had been shown to lower prostacyclin in the urine." (Graziano Decl., Ex. 132: Scolnick Tr. at 890:10-23.) Reicin stated that her "first impression was that what we saw was a result of Vioxx and not naproxen acting as a cardioprotective agent." (Id., Ex. 8: Reicin Tr. at 105:15-19.) On the day the VIGOR data was unblinded, Scolnick emailed the following message, whose subject was simply "vigor," to Defendant Reicin, Dr. Deborah Shapiro and Dr. Alan Nies:[4]

> To all: **I just received and went through the data . . . . The CV events are clearly there.** Since no obvious correlate right now ie not steroids, maybe smoking and prior a bit this is real. It is important to find out about the [lupus] cases that oates told us about. When we present in May we should present those also if he will let us do it so it is clear to the world that this is [a] class effect . . . . **It is a shame but it is a low incidence and it is mechanism based as we worried it was.** Oates and Alan [Nies] and barry [Gertz] were right about the metabolite meanings ie urine Pg [prostaglandin] data. It is important that they not appear to be different. This will limit the class somewhat but the GI safety is superb . . . .

[4] Dr. Shapiro was the Senior Director of Biostatistics and Research Sciences at Merck. Dr. Nies was the Senior Vice-President of Clinical Sciences in Merck Research Laboratories and head of the Vioxx Project Team.

> In May we need to be able to present in total pciture [sic] that is OA safety data base from all studies-ours and ushh. and postmarketing so we can frame 25mg in OA vs 50mg in RA. And that is why we need a 25mg in OA study for more safety. End point studies tell the truth. We have a great drug, and like angioedema with vasotec and seizures with primaxin and myopathy with mevacor, there is always a hazard. The class will do well and so will we.

(Id., Ex. 211) (emphasis added). Scolnick later testified, at his deposition, that when he remarked that the VIGOR results showed a greater incidence of CV events in the Vioxx arm because "it is mechanism based as we worried it was," he was referring to the Protocol 023 data regarding the prostacyclin-thromboxane imbalance.

Nevertheless, because VIGOR involved two active comparators (as opposed to Vioxx and placebo), Merck scientists, including Reicin, began to discuss an alternative hypothesis to explain the study's CV data: that naproxen administered at 500 mg daily could have a cardioprotective effect and thus be responsible for the lower incidence of CV events in VIGOR's naproxen arm. This idea came to be known as the "naproxen hypothesis."

In the days following the internal disclosure of the Vigor results, Merck undertook a review of CV events reported in other Vioxx trials. This review included the data from all Vioxx osteoarthritis trials, in which the drug had been compared to other NSAIDs and to placebo. It also included the post-marketing reports of CV events in patients taking Vioxx in a non-study setting. On March 12, 2000, Merck partially unblinded data from two ongoing Alzheimer's trials, which studied Vioxx versus placebo in an elderly population, in order to gather information about the adverse CV events in those trials. Merck asserts that it found no evidence, from its review of these datasets, that Vioxx was increasing the rate of CV events.

At the same time, Reicin and others at Merck reviewed extant scientific support for the naproxen hypothesis. Merck scientist Barry Gertz brought to Reicin's attention the data from

Protocol 061, a pre-approval clinical study of Vioxx, as indicative that naproxen may be cardioprotective, unlike other NSAIDs.[5] On March 12, 2000, Reicin sent Scolnick and Nies an email with an abstract for a study of flurbiprofen, another Cox-1/Cox-2 inhibiting NSAID, which she described as "the abstract for the only study I could find which assessed the potential cardioprotective effects of an NSAID." (Graziano Decl., Ex. 219.) Reicin testified that she believed that data showing that NSAIDs had anti-platelet effects supported the view that naproxen could be a cardioprotective agent. A meeting was held the day after Reicin circulated the flurbiprofen study, but according to the discussion, Merck lacked clarity as to the implications of VIGOR results. According to the meeting minutes, Scolnick stated that the "issue is differential effect on prostacyclin vs. thromboxane. Knocks down endothelial prostacyclin levels. Can't tell whether naproxen is improving things or VIOXX is making it worse." (Id., Ex. 226.) Then, on March 24, FitzGerald emailed Nies the results of an epidemiological study he described as "the best comparative clinical data on MI [myocardial infarction] and NSAIDs that i am aware of," adding that the study showed that individual NSAIDs had no significant effect on heart attacks, though among these "INSIGNIFICANT effects naproxen looked best . . . ." (Id., Ex. 227) (all caps in original). Reicin received a copy of FitzGerald's comments regarding the study on NSAIDs and heart attacks.

[5] Protocol 061 was a partially-blinded, randomized study of Vioxx's selectivity in inhibiting Cox-2 versus Cox-1 as compared to various NSAIDs.

E. Public Statements about VIGOR

Merck made the VIGOR results public in a March 27, 2000 press release. The press release reported the study's positive information about the reduced risk of serious GI events with Vioxx. It also reported the observed disparity in CV events between the Vioxx and naproxen arms of the study, attributing the results to naproxen's anti-platelet function and likening the "potential" cardioprotective effect of naproxen to aspirin's ability to inhibit platelet aggregation. In other words, according to Merck, the VIGOR CV results were explained by the naproxen hypothesis. The press release stated, in relevant part, as follows:

> **In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation.** This effect on these events had not been observed previously in any clinical studies for naproxen. Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects. As a result, Merck is notifying investigators, who are conducting other Merck studies with Vioxx or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspirin where appropriate. Patients using low-dose aspirin, which also blocks platelet aggregation, were excluded from the GI outcomes study. Vioxx does not interfere with the ability of low-dose aspirin to block platelet aggregation.
>
> ***
>
> Researchers believe that NSAIDs work by inhibiting two related enzymes: COX-1, the enzyme that helps maintain the stomach lining and promotes platelet aggregation, and COX-2, the enzyme that triggers pain and inflammation. At therapeutic doses, Vioxx works by selectively inhibiting COX-2 without inhibiting COX-1; non-selective NSAIDs like naproxen inhibit both COX-1 and COX-2. **Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection.**
>
> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with Vioxx,

> showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs.
>
> Further analyses are ongoing, and final results of the GI outcomes study with Vioxx will be presented at peer-reviewed medical meetings this year.

(DeMasi Decl., Ex. 104) (emphasis added).

Merck continued to make statements throughout the Class Period attributing the VIGOR results to naproxen's cardioprotective qualities. By and large, the statements reiterate Merck's support for the naproxen hypothesis and its confidence in the CV safety of Vioxx. Some statements assert that Merck's other studies show no evidence that Vioxx has a thrombotic effect.[6]

During the Class Period, the FDA took notice of Merck's repeated presentation of the naproxen hypothesis in its public statements concerning Vioxx. On September 17, 2001, the FDA sent Merck a warning letter concerning Merck's one-sided explanation for the VIGOR findings. The letter stated:

[6] In addition to its review of data from other trials in the immediate aftermath of the VIGOR results, Merck also undertook a meta-analysis of information collected from its various Vioxx clinical trials "that included a placebo or non-naproxen NSAID comparator" as well as data from the Alzheimer's studies. (DeMasi Decl., Ex. 133 at 931.) The purpose of the meta-analysis was to determine whether CV events reported in these placebo-controlled studies indicated that Vioxx had a prothrombotic tendency. Results were initially submitted to the FDA in January 2001 and updated several times, including an update as late as March 2004. Articles on the meta-analysis, co-authored by Reicin, other Merck scientists and external collaborators, were also published in Circulation in November 2001 and in the American Heart Journal in October 2003.

> **You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx.** Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).
>
> Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. **You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.**

(Graziano Decl., Exhibit 466) (emphasis added).

F. Merck's CV Study and Withdrawal of Vioxx from the Market

Thereafter, at Merck's December 11, 2001 Annual Business Briefing, Scolnick announced that Merck would conduct a CV outcomes study of Vioxx, with the goal of resolving the question of whether it was pro-thrombotic. The company simultaneously issued a press release stating that Merck announced at the meeting, attended by approximately 300 securities analysts, that it planned to conduct a large-scale clinical study of CV outcomes. Merck worked with a prominent third-party cardiologist from Harvard on designing such a trial, which came to be known as "VALOR," the acronym for "Vioxx and Aspirin in Long Term Outcomes Research." The VALOR study would compare Vioxx versus placebo in high risk patients, with both arms receiving aspirin for cardioprotection. Merck scientists and management discussed

VALOR in early 2002, identifying certain drawbacks of the study, including the susceptibility of the patient population to adverse CV events and, given the study-wide administration of prophylactic aspirin (a non-selective Cox inhibitor), the study's inability to test the FitzGerald Hypothesis. On March 26, 2002, Merck decided not to conduct the VALOR study. Instead, it performed an analysis of pooled CV data from three placebo-controlled but non CV-outcomes clinical trials.

One of these non-CV trials was known as APPROVe. It compared Vioxx at a 25 mg dose to placebo, and its purpose was to study Vioxx's ability to prevent the recurrence of colon polyps. On September 17, 2004, the APPROVEe study's External Safety Monitoring Board ("ESMB") met to review the ongoing trial's cumulative safety data. It observed significant between-treatment differences in many categories of adverse events, specifically, a disparity in confirmed thromboembolic events, some of which were fatal. Upon reviewing this data, the ESMB unanimously recommended that Merck's Executive Committee be unblinded to APPROVe's safety data and that the study be discontinued.

On September 30, 2004, Merck announced Vioxx's immediate withdrawal from the worldwide market. The press release issued that day quoted Merck's CEO at the time, Raymond Gilmartin, who explained that Merck was voluntarily taking such action in light of the "availability of the alternative therapies, and the questions raised by the [APPROVe study] data." (Graziano Decl., Ex. 13.) It also quoted Peter Kim, head of Merck Research Laboratories, as saying that "the cause of these results is uncertain at this time." (Id.) On that day, Merck's stock price dropped over $12.00 per share.

III. DISCUSSION

A. Section 10(b) Claim for Securities Fraud

Plaintiffs' Section 10(b) securities fraud claim is based on over 30 statements, which Plaintiffs allege Merck, Reicin and/or Scolnick made in violation of Securities and Exchange Commission ("SEC") Rule 10b-5(b). See 15 U .S.C. § 78j(b) (providing that "it shall be unlawful for any person . . . to use or employ, in connection with the purchase or sale of any security, ... any manipulative or deceptive device or contrivance in contravention of [SEC] rules and regulations . . . ."). Rule 10b-5(b) makes it unlawful for any person to "make any untrue statement of material fact or to omit to state a material fact in order to make the statements made, in light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5(b). A private cause of action for damages sustained as the result of a violation of Section 10(b) and Rule 10b-5(b) requires the plaintiff to establish the following six elements:

(1) a material misrepresentation or omission;

(2) scienter, i.e., a wrongful state of mind;

(3) a connection with the purchase or sale of a security;

(4) reliance, also known as "transaction causation" in cases involving public securities markets;

(5) economic loss; and

(6) loss causation, i.e., a causal connection between the material misrepresentation and the loss.

Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005). Merck argues that, pursuant to Federal Rule of Civil Procedure 56(a), it is entitled to summary judgment on the entirety of the

Section 10(b) claim because Plaintiffs will be unable at trial to carry their burden of establishing the element of scienter as to any of the allegedly misleading statements and omissions.

Federal Rule of Civil Procedure 56(a) provides that the "court shall grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Merck maintains that the evidence of record does not give rise to a genuine factual issue as to whether Defendants acted with the required state of mind in making the allegedly fraudulent statements and omissions. A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). In considering a motion for summary judgment, a district court "must view the evidence 'in the light most favorable to the opposing party.'" Tolan v. Cotton, 134 S. Ct. 1861, 1866 (2014) (quoting Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970)). It may not make credibility determinations or engage in any weighing of the evidence. Anderson, 477 U.S. at 255.

While the parties disagree as to whether there is sufficient evidence of scienter to create a genuine issue of fact, they all recognize the well-established Third Circuit definition of scienter, the state of mind a defendant must have to be liable under Section 10(b) and Rule 10b-5. "Scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind." Inst. Invs. Grp. v. Avaya, Inc., 564 F.3d 242, 252 (3d Cir. 2009). For purposes of a Rule 10b–5 claim, "[a] reckless statement is one involving not merely

simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Id. at 267 n. 42 (quoting In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535 (3d Cir.1999)) (internal quotations omitted).

Consistent with its analysis of the claim under Rule 12(b)(6) in its August 8, 2011 Opinion, the Court divides its discussion of whether the Section 10(b) claim survives this summary judgment motion into two sections. The first will address the four allegedly fraudulent statements made by Merck in the time period before the results of the VIGOR study were publicly announced on March 27, 2000 (the "pre-VIGOR statements"). The second section will analyze the evidence of scienter as to the remaining statements made after the VIGOR results were made public (the "post-VIGOR statements").

1. Pre-VIGOR Statements

Merck correctly argues that the record lacks evidence which would permit a reasonable jury to find that Defendants made the pre-VIGOR statements with the wrongful state of mind required to establish a securities fraud violation. The four pre-VIGOR statements consist of the following:

1. Merck's May 21, 1999 press release announcing FDA approval of Vioxx and stating that "[t]he most common side effects reported in clinical trials with Vioxx were upper-respiratory infection, diarrhea and nausea."
2. Merck's October 25, 1999 press release, regarding an osteoarthritis clinical trial comparing Vioxx, ibuprofen and placebo, in which Merck stated: "In this study, the most commonly reported side effects were similar in each treatment group and included upper respiratory infection, diarrhea and abdominal pain." The press release further stated that

"[i]n other studies, the most common side effects reported in clinical trials with Vioxx were upper-respiratory infection, diarrhea, nausea and high blood pressure."

3. Merck's November 23, 1999 press release, which stated: "Common side effects reported in clinical trials with Vioxx were upper-respiratory infection, diarrhea, nausea and high blood pressure." This press release was issued to provide information about a study showing a reduced risk of GI side effects for Vioxx as compared to three other NSAIDs that were not selective Cox-2 inhibitors.

4. Merck's SEC Form 10-K for the fiscal year ended December 31, 1999, which stated, in relevant part: "With its product profile for strength, safety and once-daily simplicity, Vioxx remains the country's fastest growing prescription arthritis medicine."[7]

Plaintiffs contend that the pre-VIGOR statements were misleading in light of Defendants' "concerns" that Vioxx "posed a CV risk," which were concealed from the public even as Merck chose to tout the safety profile of Vioxx. (Opp. at 59-60.) Plaintiffs do not dispute, as Merck points out, that the record is devoid of evidence that Defendants knew these statements were false, that is, that Defendants made these assertions actually knowing, at the time, that Vioxx

[7] The Court notes that none of the pre-VIGOR statements express Defendants' *opinion or belief* in some assertion about Vioxx. Rather, they make direct assertions about Vioxx. For this reason, this section of the Court's analysis calls for no discussion of the Supreme Court's recent opinion in Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund, in which the Court addressed the matter of how a statement of opinion (as opposed to a statement of fact) can constitute a misrepresentation in connection with a public offering of securities in violation of § 11 of the Securities Act of 1933. See 135 S. Ct. 1318 (2015). While the parties brought the decision to the Court's attention in post-briefing supplemental submissions, Omnicare, actually, is not directly applicable to any aspect of the instant motion for summary judgment, which deals with § 10(b) of the Exchange Act and its scienter requirement. Nevertheless, Omnicare's analysis of its discussion of misleading opinions is, to some extent, instructive on the viability of Plaintiffs' claim as to the opinion-based post-VIGOR statements, and this Court will discuss the Supreme Court's decision below.

raised a patient's risk for an adverse CV event. There is, indeed, no indication that anyone at Merck, including Defendants Reicin or Scolnick, possessed information demonstrating that Vioxx was prothrombotic when these statements were made.

Plaintiffs nevertheless maintain that a jury could find that Defendants were reckless in failing to speak accurately about the drug's safety profile. Even so, Plaintiffs do not contend that Merck's wrongful state of mind is evident from a disregard of information showing that Vioxx patients (in clinical trials or, after the product launch, non-study consumers) experienced an elevated risk of suffering an adverse CV event. Rather, they argue that the danger of misleading the public was known to Defendants, or at the very least was so obvious it should have been known to them, because Merck made the pre-VIGOR statements without testing the *potential* link between Vioxx and increased CV risk. In other words, to avoid misleading the public, Plaintiffs maintain Merck should have investigated further to either confirm, or dispel, the concerns expressed internally at Merck.

As evidence of Defendants' recklessness in deceiving the public, Plaintiffs point to the following: (1) Merck's knowledge of the Protocol 023 results showing a thromboxane-prostacyclin imbalance; (2) the FitzGerald Hypothesis regarding the possible CV effects of selective COX-2 inhibition; (3) various recommendations made by third-party consultants, including Merck's BSA, that further studies be performed to gain a greater understanding of the Protocol 023 data; (4) observations of CV events occurring in two pre-approval clinical studies of Vioxx (Protocol 010 and Protocol 017); and (5) the findings of the Watson Analysis. Plaintiffs take the position that Merck's awareness of signs indicating the possibility that Vioxx might have a thrombotic effect and failure to conduct studies that would have, in Plaintiffs' view,

"revealed the truth" about Vioxx constitute evidence of Merck's reckless state of mind in making the pre-VIGOR statements.

This evidence, however, at best amounts to an attenuated and in fact purely hypothetical connection between Vioxx and thrombosis. Even viewed in the light most favorable to Plaintiffs, Merck's awareness and, to use Plaintiffs' characterization, disregard of these signs of a safety issue in no way could permit a reasonable juror to find that Merck's pre-VIGOR statements were made with reckless disregard of the danger of misleading investors about the CV safety of Vioxx. Plaintiffs point to no clinical trials during this time period which yielded data on the incidence of adverse CV events in Vioxx users that would indicate a serious side effect. The evidence, to the contrary, shows discussion and study of the available data and the repeated assessment that it raised important questions but provided an insufficient basis for any conclusions about CV effects in patients. To attribute a wrongful state of mind to Defendants with respect to the pre-VIGOR statements, a jury would have to engage in speculation and conjecture about what Defendants should have extrapolated from the information Merck had at the time. The record simply does not show that Merck possessed information in the pre-VIGOR period that associated Vioxx with an increased CV risk.

Even the Watson Analysis, which was aimed at analyzing the incidence of CV events in Vioxx studies, fails to lend support to Plaintiffs' position that Merck recklessly deceived investors regarding Vioxx's CV risks. The Watson Analysis was not a placebo-controlled study of Vioxx but rather a comparison of data from all individuals enrolled in the mainly ongoing Vioxx studies to data from those in the placebo arms of the completed studies of two other Merck drugs, Fosamax and Proscar. Plaintiffs make much of the study's finding that women enrolled in Vioxx trials experienced a higher incidence of CV events than women in a placebo

arm of the Fosamax study. This isolated comparison does not demonstrate that Vioxx was prothrombotic and, more to the point, that Merck recklessly ignored data indicating a serious side effect of Vioxx. The information must be put in context. The Vioxx trials providing the data analyzed by Watson remained, in large part, blinded, and thus the patient groups experiencing these events was unknown and unknowable. The reported CV events could not be correlated to the Vioxx arms of those studies, versus placebo or some active comparator, such as another NSAID. Moreover, the Watson Analysis in fact concluded that that there was no clear evidence that participants in the Vioxx trials experienced a consistent elevated risk of a CV event as compared to the placebo controls Watson reviewed from the Proscar and Fosamax trials. In short, the knowledge possessed by Merck at the time the pre-VIGOR statements were made does not support the existence of a reckless state of mind, which the Third Circuit has held must, in the context of securities fraud, be akin to an intent to deceive. S.E.C. v. Infinity Grp. Co., 212 F.3d 180, 192 (3d Cir. 2000).

Plaintiffs' argument regarding the existence of scienter boils down to the view that Defendants' recklessness lies in making assertions about Vioxx's safety profile and side effects without having first confirmed that, contrary to a hypothesis about the clinical consequence of selective Cox-2 inhibition, Vioxx did not increase the risk of a CV events. In other words, Plaintiffs argue that scienter may be established based on Merck's failure to study whether Vioxx has a thrombotic effect in patients. They rely on this Court's opinion in In re Bristol-Myers Squibb Securities Litigation ("BMS"), citing it for the proposition that a securities fraud defendant's failure to conduct studies regarding a potential serious side effect of a product in development can constitute evidence of scienter when the defendant speaks about the product without disclosing those concerns. See In re Bristol-Myers Squibb Sec. Litig., No. 00-1990

(SRC), 2005 WL 2007004, at *39 (D.N.J. Aug. 17, 2005). Plaintiffs characterize BMS as holding that a defendant's reckless state of mind can be established by showing that the absence of information that would prove its statements to be false or misleading stems from the defendant's own decision to disregard problematic data and failure "to perform analyses that it 'could have and should have' conducted that would have revealed the truth . . . ." (Opp. at 30) (quoting BMS, 2005 WL 2007004, at *30.)

Looking at the BMS decision carefully, however, it becomes apparent that the facts of that case are vastly different from the facts relating to Defendants' pre-VIGOR statements. Among other statements giving rise to the Section 10(b) claim in BMS, BMS had issued two press releases regarding Vanlev, a drug in development, which listed the "most-commonly reported side-effects" in "placebo-controlled clinical trials" but omitted "the company's concern with angioedema." Id. at 39. The BMS court held that because there was evidence that, at the time these statements were made, the incidence and severity of angioedema in placebo-controlled clinical trials was the subject of substantial attention and concern at BMS, a reasonable jury could infer that the defendants knew or were reckless in not knowing that the statements were misleading. Id. The evidence underlying the "concern" at BMS with angioedema, such that a jury could conclude that BMS was reckless as to the truth of its statement about the drug's side effects, included the observation of a higher incidence of angioedema in clinical trials of Vanlev as compared to placebo or comparator hypertension drugs. Id. at *3-4, *33-34. In particular, BMS had conducted an all-African-American clinical trial which showed that African-American women taking Vanlev experienced over 10 times the

number of angioedema complications than those taking the comparator hypertension drug in the study. Id. at *4, *34. Moreover, the record contained evidence that BMS was aware that during the clinical development of the drug, there were four cases of life-threatening angioedema. Id. at *3.

Plaintiffs' selective and out-of-context use of snippets from the BMS opinion glosses over the significant difference between the information known to BMS when it failed to disclose angioedema as a side effect and the information known to Merck when it spoke about Vioxx's most common side effects and safety profile in the pre-VIGOR statements. In BMS, the defendant was aware of the actual occurrence of a serious side effect in clinical trials of the drug, including a ten-fold increase over the comparator in one particular patient group. In this case, Merck's knowledge of any purported link between Vioxx and adverse CV events amounts to nothing more than a concern, based on urinary metabolite data collected in one study, which might hypothetically indicate a problem. The information available to Merck about Vioxx at the relevant time is a far cry in nature and degree from the observed "incidence and severity" of a complication in patients participating in placebo-controlled clinical studies, as was the case in BMS.

Plaintiffs' theory of scienter depends on the premise that Merck's conduct with regard to the study and testing of Vioxx can be seen as "an extreme departure from the standards of ordinary care" such that its pre-VIGOR statements were made with "reckless disregard of the truth" about Vioxx. Infinity Grp., 212 F.3d at 192. As set forth above, there is no evidence that Merck made the statements with "reckless disregard for the truth," that is, according to Plaintiffs, that Vioxx was prothrombotic and increased CV risk. To reiterate, the high standard of recklessness with regard to securities fraud requires that the danger of misleading buyers through

a defendant's statements or omissions must be "either *known* to the defendant or is *so obvious* that the actor must have been aware of it." Id. Rule 10b-5, pursuant to which Plaintiffs bring this Section 10(b) claim for securities fraud, regulates the making of statements, not the conduct of a company in its other business functions, in this case, a pharmaceutical company's development and testing of a drug. To the extent Plaintiffs argue that that a jury could infer scienter from evidence of allegedly insufficient research and investigation of a drug, they are, without legal authority, pushing the scope of a securities fraud claim into an area regulated by the FDA.

Simply put, Defendants have demonstrated that the record lacks evidence which would permit a jury to conclude that, based on the information available to Merck at the time the pre-VIGOR statements were made, Merck knowingly or recklessly deceived the public about Vioxx. Plaintiffs, for the reasons discussed, have failed "to make a showing sufficient to establish the existence of an element essential to [their] case," in particular the Section 10(b) claim's element of scienter. Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992). Accordingly, insofar as Plaintiffs' Section 10(b) claim is based on the four pre-VIGOR statements, summary judgment in favor of Defendants is warranted.

2. Post-VIGOR Statements

In all, there are 29 alleged misrepresentations and/or omissions of material fact about Vioxx made by Defendants in the post-VIGOR period. They generally consist of statements (1) expressing Merck's backing of the naproxen hypothesis over the possibility that Vioxx might increase the risk of an adverse CV event; (2) asserting that Merck had no evidence indicating that Vioxx had a thrombotic effect; and (3) reassuring the public that, based on the available data, Merck stood behind the safety of Vioxx, including, specifically, its cardiovascular safety. The

first post-VIGOR statement consists of the March 27, 2000 press release, quoted above, which asserted, among other things, that VIGOR's results were "consistent with the naproxen's ability to block platelet aggregation."

In the interest of brevity, the Court will not quote each and every post-VIGOR statement at issue. Instead, it will highlight some of the representative or notable statements made by Merck, Reicin and/or Scolnick after the March 27, 2000 press release was issued. They are as follows:

- In November, 2000, the New England Journal of Medicine ("NEJM") published an article concerning the VIGOR study. The article was co-authored by Reicin, Shapiro and various non-Merck scientists. It reported a "significantly lower" myocardial infarction rate in the naproxen group versus the Vioxx group and noted that "the effects of regular use of naproxen may be similar to those of aspirin."
- The NEJM article also put forth an explanation for the VIGOR results referred to in the briefs as the "4% VIGOR Subgroup" claim. The claim, which had first been offered by Merck in a May 2000 press release, maintains that the disparity in myocardial infarction incidence between the Vioxx and naproxen arms of the VIGOR study was mainly due to the fact that 4% of the study patients were indicated for aspirin prophylaxis, given the patients' greater risk for heart attack, but did not receive it. The NEJM article asserted that this 4% subgroup accounted for 38% of myocardial infarctions observed in the trial, whereas in the other 96% of patients "the difference in the rate of myocardial infarction between groups was not significant . . . ."

- Merck issued a press release on February 8, 2001 regarding the FDA Arthritis Advisory Committee meeting regarding Merck's application to revise the Vioxx label to include the GI data from VIGOR. The press release stated, in relevant part, as follows:

> Although the VIGOR study was a GI outcomes study and was not designed to show differences in cardiovascular effects, significantly fewer heart attacks were observed in patients taking naproxen (0.1 percent) compared to the group taking Vioxx 50 mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen. Patients taking aspirin did not participate in VIGOR. In extensive discussions, the Advisory Committee explored this finding, other studies of Vioxx and possible explanations for this result in VIGOR. In the completed osteoarthritis trials and on-going clinical trials with Vioxx 12.5 mg, 25 mg and 50 mg in 30,000 patients, there was no difference [emphasis in original] in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo.
>
> Merck scientists said the VIGOR finding is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1 like aspirin, which is used to prevent second cardiac events in patients with a history of heart attack, stroke or other cardiac events. This is the first time this effect of naproxen on cardiovascular events has been observed in a clinical study. Other explanations were advanced by the FDA reviewer and were discussed with the Advisory Committee. The Committee recommended that the data on cardiovascular events in VIGOR be included in the labeling for Vioxx.

- In a press release issued on June 13, 2001, Merck stated that, after learning the VIGOR results, it conducted a meta-analysis of data from 19 clinical studies of Vioxx, measuring the results of those studies using a combined endpoint of unknown or cardiovascular death, stroke or heart attack. The press release reported that "the relative risks of serious cardiovascular events were similar with Vioxx and placebo" and with Vioxx and various NSAIDs. It further stated the "the event rate with naproxen was lower than with Vioxx"

and went on to attribute this finding to naproxen's anti-platelet effect, which the press release described as the same property responsible for aspirin's cardioprotective quality.

- Scolnick commented on the VIGOR results in an October 9, 2001 New York Times article, which published the following quote: "There are two possible interpretations . . . Naproxen lowers the heart attack rate or Vioxx raises it . . . the likeliest interpretation of the data is that naproxen lowered lowered [sic] the thrombotic event rate."
- A Merck press release dated April 11, 2002 announced that the FDA had approved label changes to reflect the VIGOR results and had approved a new indication for Vioxx for adult rheumatoid arthritis. In reporting that the label had been revised to include cardiovascular data, the press release stated, among other things, that "the significance of the cardiovascular findings from these three studies (VIGOR and the placebo-controlled studies) is unknown. Vioxx is not a substitute for aspirin to prevent cardiovascular events because of its lack of effect on platelets."
- The April 11, 2002 press release included the following quote from Scolnick, in the context of announcing that the Vioxx label would contain VIGOR's cardiovascular data: "Merck is confident in the efficacy and safety profile of Vioxx. VIGOR was a rigorous test of the GI safety of Vioxx versus naproxen and based on that study, the FDA has approved a modification to the standard GI warning section."
- In an October 30, 2003 Wall Street Journal article, Reicin commented on the findings of a Merck-funded study conducted by Brigham & Women's Hospital. The study reviewed the records of over 50,000 Medicare patients, all over age 65, and compared outcomes for those on Vioxx versus competing Cox-2 inhibitor Celebrex. It found an increased risk of myocardial infarction in patients taking Vioxx. Reicin questioned the validity of the

findings because the study was not a "randomized clinical trial." In contrast, she added "In our [Merck's] placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo."

- Merck issued a press release on August 26, 2004 to respond to the conclusions of an observational analysis, funded by the FDA, which reviewed the records of Kaiser Permanente patients in California and found an increased incidence of cardiovascular events in patients taking Vioxx compared to other NSAIDs. The press release stated that "Merck strongly disagrees with the conclusions of [the Kaiser Permanente] observational study." It also stated: "This analysis is a retrospective database analysis—not a clinical trial. Observational analyses have limitations, often conflict with each other, and must be interpreted within the context of data from large, randomized, controlled clinical trials. Randomized, controlled clinical trials are the gold standard to evaluate safety and efficacy." The press release quoted Peter Kim, at that time head of Merck Research Laboratories (after Scolnick's retirement), who said: "The robust clinical trial data available support the safety of VIOXX. Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX."

A recurring expression throughout the post-VIGOR statements is Merck's support of the naproxen hypothesis. According to Plaintiffs, Defendants spoke about this matter with the requisite scienter because, even assuming they actually believed that naproxen was cardioprotective and that this quality explained VIGOR's CV data, Defendants lacked a reasonable basis for holding such an opinion. Plaintiffs' theory of scienter with regard to Defendants' statements of belief in the naproxen hypothesis is that their opinion was not a

reasonable and good faith interpretation of the information known to them and, thus, Defendants deliberately misled investors by implicitly asserting that the naproxen hypothesis, though admittedly unproven, was grounded in fact. In particular, as the Opinion will review below, Plaintiffs point to evidence that Scolnick and Reicin were aware of the paucity of scientific support for the naproxen hypothesis and that they disregarded contrary information. Plaintiffs also argue that Defendants' knowing and/or reckless state of mind in making post-VIGOR statements about Vioxx's CV safety is demonstrated by their manipulation of data to make such assertions, such as the 4% VIGOR Subgroup claim and the assertion that Merck's other Vioxx studies indicate no increased CV risk.

Merck, in contrast, characterizes the event setting the post-VIGOR period in motion—the March 9, 2000 unblinding of the VIGOR study results—as the initiation of an intense scientific debate, both among the scientific community generally and within Merck internally, about the cause of the disparity in CV events between the study's Vioxx arm and naproxen arm. It emphasizes that the competing hypotheses, that is, that Vioxx is prothrombotic or that naproxen is cardioprotective, continue to be discussed among scientists today. Merck concedes that the initial reaction to the unblinding of the VIGOR results, in particular by Reicin and Scolnick, indeed reflects that Defendants understood the results to expose a negative CV effect of Vioxx. Defendants maintain, however, that they came to be satisfied with the naproxen hypothesis as the best or likeliest explanation for the VIGOR results by the time Merck issued its first post-VIGOR statement, the March 27, 2000 press release. The record, they argue, demonstrates that their interpretation was based on sound scientific information, and moreover, that their subjective belief in the naproxen hypothesis throughout the post-VIGOR period remained grounded in their reasonable analysis of the data.

The Court recognizes that Defendants have proffered evidence in support of their arguments. They have not, however, carried their Rule 56 burden of demonstrating that no reasonable jury could find that Scolnick, Reicin and, derivatively, Merck, intentionally and/or recklessly misled the public. In this motion for summary judgment, Plaintiffs and Defendants use the same factual record to tell two very different stories about the manner in which Scolnick and Reicin arrived at their conclusions about the VIGOR results and about Vioxx's CV safety profile generally. The proof-based narratives they present to the Court arrive at vastly different conclusions about Defendants' state of mind in making the post-VIGOR statements.

The parties do share a common jumping-off point. They agree that, after their initial assessment that VIGOR revealed a prothrombotic effect of Vioxx, Reicin, Scolnick and others at Merck investigated whether there might be an alternative explanation. It is at this juncture that that the parties' respective interpretations of the events that follow begin to diverge. Given that on a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-moving party, the Court will highlight items in the record that give rise to a genuine issue of fact as to Defendants' scienter.

Plaintiffs proffer evidence that, prior to approving the press release issued by Merck on March 27, 2000, Reicin and Scolnick were aware that there was little to no scientific evidence demonstrating, or even suggesting, that naproxen was cardioprotective. In particular, support for the hypothesis consisted of (1) a small study of a non-naproxen NSAID and (2) a paper relating to an epidemiological study of NSAIDs and myocardial infarctions, which, according to FitzGerald, did not demonstrate that naproxen had a significant cardioprotective effect. Patrono, who served as a Merck consultant during this time period, testified at his deposition that while, "at the time there was a general assumption that traditional NSAIDs would be cardioprotective,"

"there was no evidence either from randomized clinical trials or from observational studies." (DeMasi Decl., Ex. 40: Patrono Dep. 32:4-14.) On the topic of the VIGOR results, Scolnick expressed at a March 13, 2000 meeting that, based on the available information, the cause of the disparity in CV events between study groups could not be determined. Plaintiffs also present evidence that Reicin had been warned that data from Vioxx osteoarthritis and Alzheimer's trials, which she reviewed for any indication of a Vioxx-CV link, lacked adequate statistical power to detect CV risk.

Nevertheless, the press release asserted that VIGOR's results were "consistent with naproxen's ability to block platelet aggregation." It further stated that Merck's other Vioxx studies showed no indication that Vioxx was prothromobotic. A reasonable jury could find scienter based on Defendants' initial negative interpretation of the VIGOR results and the lack of evidence to support their assertion that naproxen's cardioprotective quality accounts for the results.

Further giving rise to an issue of fact as to Defendants' state of mind, Plaintiffs have presented evidence that previous drafts of the March 27, 2000 press release acknowledged that the cause of the greater incidence of CV events in the Vioxx patient group over the naproxen patients was unknown. An early draft stated that "It is unclear whether these results reflect an adverse effect of rofecoxib (at the 50 mg dose) or an antiplatelet (protective) effect of naproxen, and not an adverse effect of rofecoxib." (Graziano Decl., Ex. 239.) This language was then changed in favor of "we believe these results reflect an antiplatelet (cardio-protective) effect of naproxen, and not an adverse effect of rofecoxib." (Id., Ex. 241.) Ultimately, the final draft eliminated any mention of the possibility that Vioxx (rofecoxib) might have a thrombotic effect. Viewing this evidence in the light most favorable to Plaintiffs, a jury could find that the

assertions made by Merck in the March 27, 2000 press release were knowingly or recklessly false.

With regard to Defendants' state of mind as to other statements made throughout the remainder of the Class Period, the record contains evidence that Reicin and Scolnick continued to be presented with data undermining the naproxen hypothesis. For example, Merck consultant Patrono opined that he did not believe the VIGOR results could be attributed to the naproxen hypothesis, because, according to an email summarizing his comments, "there is a weak pharmacological basis and no epidemiological evidence" for it. (Graziano Decl., Ex. 7.) He also stated that "the magnitude of the effect [the reduced risk of CV event in the naproxen arm] would not be plausible even if the comparator had been aspirin itself." (Id.) Patrono's comments were communicated to Reicin and Scolnick in a March 28, 2000 email.

Later that year, at an October 30, 2000 meeting between Merck and its consultants, Patrono repeated this assessment. At the meeting, FitzGerald similarly noted that the "magnitude of effect is 2x what expected if naproxen was aspirin" and warned that the "NSAID hypothesis for cardioprotection has not been proven (data are actually negative) . . . ." (Graziano Decl., Ex. 279, 280 at MRK-ACF009165.) Oates, also in attendance, stated that the magnitude could be attributable to "both protective effect of naproxen and harmful of rofecoxib at same time (magnitude)." (Id., Ex. 279.) He also stated, "Is naproxen = aspirin. I don't know, but the magnitude of the effect is greater than anticipated, so I don't think that the loss of prostacyclin can be discounted." (Id., Ex. 280 at MRK-ACF009165.) Reicin was present at the October 30, 2000 meeting.

Plaintiffs have also presented evidence that, in internal emails and other communications, Scolnick expressed his doubts about attributing the VIGOR results to the naproxen hypothesis.

After further review of the VIGOR data, Shapiro emailed Reicin, Scolnick and others on March 31, 2000 to report that while there was a four-fold increase in the rate of myocardial infarctions associated with Vioxx versus naproxen, no difference in the incidence of stroke had been observed. Scolnick responded, on April 1, 2000, that in light of this data, "the prostacyclin/thromboxane hypothesis is further strengthened . . . Only more work will clarify this aspect." (Id., Ex. 305.) Later that month, Scolnick traded emails with Reicin discussing the question of whether the VIGOR results could be attributed to the study's population of patients with rheumatoid arthritis. After reviewing literature provided to him by Oates, Scolnick noted that the literature did not support that alternative explanation and further wrote in his April 12, 2000 email to Reicin that his "worry quotient was high" and that a large-scale study comparing Tylenol and Vioxx was necessary to determine whether the increased incidence of heart attacks was caused by Vioxx. He stated: "WE WILL NOT KNOW FOR SURE WHAT IS GOING ON UNTIL WE DO THIS STUDY." (Id., Ex. 274) (all caps in original). Plaintiffs point out that neither the Tylenol study, nor any other clinical CV outcomes trial was conducted by Merck in the time period between the completion of VIGOR and the withdrawal of Vioxx from the market.

Plaintiffs proffer evidence that, throughout 2001, Scolnick continued to struggle with his admitted uncertainty about the naproxen hypothesis. On January 31, 2001, Scolnick emailed Merck CEO Ray Gilmartin, in advance of the February 8, 2001 Advisory Committee meeting with the FDA. As noted earlier in the Opinion, the purpose of that meeting was to discuss modification of the Vioxx label to disclose information learned in the VIGOR study. Scolnick wrote to Gilmartin as follows:

> [T]here is no way to prove that in patients with rheumatoid arthritis that ALL of the difference between Vioxx and naproxen is due to the benefit of naproxen. IT IS IMPOSSIBLE TO PROVE THIS; IT IS IMPOSSIBLE TO KNOW THIS WITH CERTAINTY . . . . We need to face the reality of the situation and manage it.

(Id., Ex. 324) (all caps in original). In November 2001, Scolnick emailed Merck employee Douglas Greene concerning the placebo-controlled data from Merck's meta-analysis of the CV events associated with Vioxx. He wrote, "The more I get, the more nervous I become. I will schedule a meeting with you and the key people, or you can do it where we can go over all the data in a way that I really understand it before any further FDA negotiations." (Id., Ex 473.) Scolnick's email to Greene was forwarded to others, including Reicin.

In contrast to these internal expressions of doubt, Plaintiffs point out, Scolnick was reassuring the public of his confidence in the naproxen hypothesis. They emphasize that he made two separate statements during the same 2000-2001 timeframe which are completely at odds with the conversations at Merck about the data backing the hypothesis. One of these is Scolnick's statement, made at Merck's December 12, 2000 Annual Business Briefing, that "[t]he cardiovascular issues in VIGOR, even at this point compared to where we were when we first got the data are unambiguously related to a decrease in the events in the naproxen arm and not an increase in the Vioxx arm of the study . . . ." (Id., Ex. 323 at 2:1-6.) The other is his comment at the December 2001 annual meeting, where Scolnick once again expressed strong support for the naproxen hypothesis, stating, with regard to VIGOR, that the cardioprotective effect of naproxen was the "best interpretation of the data." (Id., Ex. 441 at 32:19.) While these two public statements by Scolnick are not pled in the Complaint as among the material misrepresentations on which the Section 10(b) claim is based, they nevertheless do constitute relevant evidence as to

his state of mind, and derivatively Merck's scienter, in expressing belief in the naproxen hypothesis.[8]

Perhaps one of the starkest examples in the record juxtaposing Merck's awareness of the lack of scientific support for the naproxen hypothesis and its public endorsement of this explanation for the VIGOR CV data can be found in Scolnick's October 9, 2001 statement, as quoted by The New York Times. There, he identified two possible interpretations of the VIGOR results but added that the naproxen hypothesis was the "likeliest" explanation. According to the evidence adduced by the parties, up until that point, Merck had not acknowledged, publically, that VIGOR could be interpreted as indicative of some prothrombotic risk posed by Vioxx. Instead, the statements consistently attributed the results to naproxen's cardioprotectiveness, i.e., the naproxen hypothesis. In September 17, 2001, the FDA issued its warning letter to Merck, pointedly reprimanding Merck for "selectively present[ing]" the naproxen hypothesis despite the fact that it is "hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties." (Id., Ex. 466.) A reasonable jury could conclude that, when only weeks after this warning, Merck nevertheless identified the naproxen hypothesis as not only a *possible* explanation but the *favored* one over Vioxx's tendency to increase CV risk, it knowingly deceived investors by, in essence, knowingly misrepresenting that Merck and/or Scolnick were in possession of facts justifying this opinion. Cf. Omnicare, 135 S. Ct. at 1329 (holding that an opinion expressed by a corporate defendant in a registration statement issued in connection with a public offering of securities can be

[8] The Court must note that Plaintiffs' efforts to add these two statements to the Section 10(b) claim are unavailing. The law in the Third Circuit does not allow pleadings to be amended through briefs submitted in connection with dispositive motions. Frederico v. Home Depot, 507 F.3d 188, 201–02 (3d Cir. 2007).

misleading in violation of securities laws, specifically Securities Act § 11, if it does not "fairly align[] with the information in the issuer's possession at the time.")

The Supreme Court's Omnicare decision, dealing with a securities fraud claim based on statements of opinion, illuminates this Court's Section 10(b) scienter analysis as it relates to Defendants' expressed support of the naproxen hypothesis. In Omnicare, the corporate defendants filed a registration statement with the SEC, in connection with a public offering of common stock, in which the defendants, in relevant part, made two statements giving their opinion about the company's legal compliance. Id. at 1323. The plaintiffs, who had purchased Omnicare stock in the public offering, brought suit under Section 11 of the Securities Act, which imposes liability for material misstatements and omissions in registration statements. Id. at 1323-24. (In this regard, Section 11 is similar to Section 10(b) claim, although the former does not carry a scienter requirement.) Defendant Omnicare had argued that an opinion statement may never constitute an actionable misrepresentation because, in its view, a reasonable person understands that an opinion statement conveys only the speaker's mindset, and thus, as long as the opinion is sincerely held, the statement cannot be misleading. Id. at *1328. The Supreme Court rejected this argument, in light of Section 11's omissions clause. Id. at 1328-39. It found that a statement of opinion, i.e., the speaker's belief in some fact (as opposed to the fact itself) may give rise to liability if the expressed belief is at odds with information known to the speaker. Id. The Court reasoned that "a reasonable investor may, depending on the circumstances, understand the opinion statement to convey facts about the speaker's basis for holding that view." Id. at 1328. It concluded: "if a registration statement omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and if those facts conflict

with what a reasonable investor would take from the statement itself, then § 11's omissions clause creates liability." Id. at 1329.

The Omnicare Court, moreover, noted that these principles concerning the manner in which a reasonable person understands statements of opinion and, thus, how opinions could be considered fraudulent are "not unique to §11." Id. at 1330. Rather, they are fundamental to the common law of misrepresentation, which recognizes the implied assertion of knowledge that an opinion carries. Id. The Supreme Court observed that, under the Restatement of Torts,

> "a statement of opinion as to facts not disclosed and not otherwise known to the recipient may" in some circumstances reasonably "be interpreted by him as an implied statement" that the speaker "knows facts sufficient to justify him in forming" the opinion, or that he at least knows no facts "incompatible with [the] opinion." When that is so, the Restatement explains, liability may result from omission of facts—for example, the fact that the speaker failed to conduct any investigation—that rebut the recipient's predictable inference.

Id. (quoting Restatement (Second) of Torts § 539, p. 85 (1976)) (internal citation omitted).

Thus, as Plaintiffs have argued, the Omnicare Court's analysis squares with the earlier holdings in this case, by both this Court and the Third Circuit, that Defendants' opinion concerning the naproxen hypothesis may constitute securities fraud if Defendants either subjectively disbelieved the opinion they asserted or lacked a reasonable basis for their expressed belief. See Merck, 2011 WL 3444199, at *14 (citing Merck, 543 F.3d 150, 166 (3d Cir. 2008)). Against these parameters of the statements and omissions of material fact that will be considered to defraud investors in publicly traded securities, the Court finds that the record in this case contains ample evidence to create a genuine issue of fact as to Defendants' state of mind in expressing their belief in the naproxen hypothesis. Even if sincerely held, as Defendants have argued, a reasonable investor could understand Defendants' opinion statements to convey facts

about their basis for holding the view that the cardioprotective quality of naproxen is the "likeliest" explanation for VIGOR. The record contains evidence upon which a reasonable jury could conclude that Defendants not only lacked support for this assertion of belief but, additionally, knew that it did not "fairly align" with other information in their possession. This evidence consists of, for example: Merck's internal discussions revealing a very different assessment of the VIGOR data than that expressed to the public; its receipt of contrary advice from consultants regarding the naproxen hypothesis as the proper interpretation of VIGOR; Merck's possession of data discrediting the underlying assumption that naproxen has cardioprotective qualities similar to aspirin; and the FDA's specific and unequivocal warning regarding Merck's public espousal of the naproxen hypothesis.

Merck's motion also argues that no reasonable jury could find that Reicin in particular acted with the requisite scienter, and thus, at the very least, she is entitled to summary judgment on the Section 10(b) claims. However, as with Defendants Merck and Scolnick, the record contains sufficient evidence to create an issue of fact regarding her state of mind.

Reicin was a co-author of the NEJM article published on November 27, 2000. Among other assertions, the article once again made the claim that the VIGOR results indicated that naproxen had a cardioprotective property and offered the 4% VIGOR Subgroup claim, explaining that a disproportionate number of myocardial infarctions occurred in the small group of patients indicated for cardioprotective aspirin therapy, not administered to any VIGOR participant. Plaintiffs have presented evidence that Merck's outside advisors as well as scientists within the company warned Reicin that the statement lacked a valid statistical basis and that it was misleading to emphasize the difference between the 4% Subgroup and the rest of the study's participants. Plaintiffs point out that Reicin deleted information from a draft of the paper which

reported "an increase in the rate of thromboembolic events," not only, as ultimately reported, myocardial infarctions. (Graziano Decl., Ex. 405.) They also point out that the cut-off for CV event data in VIGOR was one month earlier than the cut-off date for reporting adverse GI events. They argue that Reicin's edit, together with the early cut-off date for CV events, shows her efforts to minimize VIGOR's CV events and provides evidence of her wrongful state of mind in making the assertions of the NEJM article.

Plaintiffs also adduce evidence that Reicin altered reporting methods in connection with data from the Alzheimer's trials, which they argue indicates her awareness of negative data regarding Vioxx and increased CV risk. They show that Reicin saw that an analysis of the data according to the intention to treat ("ITT") approach (in which data on each patient is collected from the time of randomization to the date the study ends, even after treatment has been discontinued) revealed an imbalance in mortality between Vioxx and placebo, and notably an imbalance in CV deaths. In contrast, as discussed in an April 1, 2001 email between Reicin and Dr. Scott Reines, a Merck neuroscientist, the difference in mortality rates was not significant when the data was analyzed according to an "on-drug" method, in which data is collected for a shorter period of time than ITT. (Graziano Decl., Ex. 333.) Plaintiffs present evidence that Reicin decided to change the endpoint for mortality data from ITT to on-drug, even though Dr. Raymond Bain, the vice president for Merck's department of Clinical Biostatistics and Research Decision Sciences, advised her that the pre-specified ITT analysis "provides additional information and maintains more of the randomized patients." (Id.) In that same email of April 2, 2001, Bain further cautioned Reicin that "although the 'on drug' analysis was not 'statistically significant' the estimated 2-fold increase in mortality requires evaluation." (Id.) Plaintiffs argue

out that Reicin, and Merck, nevertheless represented throughout the Class Period that Merck's data showed no Vioxx-CV link.

Merck makes plausible arguments, with citations to the record, responding to Plaintiffs' points about Reicin's interpretation of the Alzheimer's studies data and other proffered instances of conduct Plaintiffs characterize as "manipulation" of data and study protocols. In its reply brief, Merck maintains that there were legitimate scientific reasons for the decisions it and its scientists made concerning the methods for analyzing data, study endpoints, and the cancellation of VALOR, the planned clinical CV outcomes study. The evidence of scienter as to Reicin and Merck, it argues, rises to no more than post-hoc scientific disagreement, which does not give rise to a securities fraud claim. Alaska Elec. Pension Fund v. Pharmacia Corp., 554 F.3d 342, 352 (3d Cir. 2009). However, it is also the law in the Third Circuit that "a bad faith misrepresentation of scientific data" can give rise to an inference of scienter sufficient to set forth a securities fraud claim. Id. The record before the Court contains evidence that would support such a finding. As such, the evidence is not "so one-sided that one party must prevail as a matter of law." Anderson, 477 U.S. at 252.

The Court further notes that Defendants raise plausible arguments in response to Plaintiffs' supplemental letter brief concerning the impact of the Omnicare holding on this case, and in particular, on the issue of scienter as presented in the instant motion for summary judgment. Of course, Defendants note the differences between the Section 11 claim at issue in Omnicare and the Section 10(b) claim brought by Plaintiffs here, in particular the lack of a scienter requirement in the claim analyzed by Omnicare. Defendants argue that even if this Court were to consider the Omnicare decision's rationale for concluding that a statement of opinion may be misleading, the record contains substantial evidence demonstrating that Defendants'

views regarding the naproxen hypothesis were not only sincerely held but were aligned with the information in their possession, i.e., were supported by a legitimate scientific basis. Again, the Court is aware of the evidence in Defendants' favor as to its position that neither its assertions of fact nor its statements of opinion concerning Vioxx were intentionally misleading.

However, the proofs bearing on Defendants' scienter as to the post-VIGOR statements are, in a word, mixed. At the summary judgment stage, the Court's role is "not ... to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249. It must, moreover, view the evidence in the light most favorable to Plaintiffs. As discussed, there is evidence that would allow a reasonable jury to find that Defendants knowingly or recklessly deceived investors by stating their belief in the naproxen hypothesis, asserting that studies and data reviewed by Merck do not indicate that Vioxx may increase CV risk, and expressing confidence in Vioxx's CV safety. Neither Merck's motion nor Scolnick's motion has carried the burden imposed by Federal Rule of Civil Procedure 56(a) to show that no reasonable trier of fact could find the element of scienter satisfied. Accordingly, to the extent Plaintiffs' securities fraud claim is based on the post-VIGOR statements, the claim against Merck, Reicin and Scolnick survives this summary judgment motion.

3. Scolnick's Additional Challenges to the Section 10(b) Claim

In addition to joining in the arguments raised by Merck in support of its motion for summary judgment, Scolnick has filed his own motion challenging the Section 10(b) claim on other grounds and moving for Rule 56(a) relief as to the insider trading claim against him. The Court will address each of these matters in turn.

First, Scolnick argues that he is entitled to summary judgment on the Section 10(b) claim on the grounds that no jury could find that the four statements on which Plaintiffs base the remaining portion of the claim against him contain a misrepresentation or omission of material fact.[9] Those statements consist of the following: (1) Merck's 1999 Form 10-K, asserting that Vioxx has a "product profile for strength, safety and once-daily simplicity; (2) the October 9, 2001 New York Times article quoting Scolnick as stating, among other things, that the naproxen hypothesis was the "likeliest" explanation for the VIGOR data (the "New York Times statement"; (3) a December 11, 2001 Bloomberg News article quoting Scolnick as asserting that Merck would conduct more research on Vioxx's CV safety so that it can be "100 percent sure" of its safety (the "Bloomberg News statement"); and (4) an April 11, 2002 press release issued by Merck, with a quotation from Scolnick that "Merck is confident in the efficacy and safety profile of Vioxx."

The first of these statements is one of the pre-VIGOR statements the Court has already concluded lacks factual support as to the element of scienter. Because it has already held that the Section 10(b) claim cannot proceed as to the pre-VIGOR statements, the Court need not consider Scolnick's arguments that no reasonable jury could find the first statement attributed to him to be false. Scolnick's arguments for summary judgment on the other three statements will be addressed in turn.

The New York Times statement, discussed at length earlier in this Opinion, is not immune from liability simply because it expresses Scolnick's opinion about the "likeliest"

[9] Scolnick begins by pointing out that in its August 8, 2013 Opinion ruling on the motion to dismiss, the Court held that of the various statements at issue, only seven are attributable to Scolnick and further held that only four of those are actionable.

explanation for the VIGOR data. As the Third Circuit has recognized, an opinion statement can be materially misleading in violation of securities fraud laws if it either does not express the actual belief of the speaker—i.e., misleads as to the fact of his belief—or lacks a reasonable basis. See City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014) (holding that the plaintiff had failed plead a misrepresentation in violation of Section 10(b) because the complaint did not allege that defendants "did not honestly believe their [opinion] or that [the opinion] lacked a reasonable basis."); In re Merck, 543 F.3d 150, 166 (3d Cir. 2008) (holding that a misrepresentation in an opinion may be actionable under Section 10(b) if plaintiff shows that the statement was "issued without a genuine belief or reasonable basis."). While Scolnick argues that Plaintiffs cannot adduce evidence that he did not genuinely hold the scientific opinion he gave in the New York Times statement, the record contains sufficient evidence to raise a question of fact on this point. Scolnick expresses, initially, the view that the VIGOR data demonstrate that Vioxx is prothrombotic, directly contradicting his stated opinion regarding the naproxen hypothesis. There is also evidence upon which a jury could conclude that Scolnick lacked confidence in the naproxen hypothesis and/or had not reviewed scientific data that would support a good faith or reasonable basis for his opinion. Cf. Omnicare, supra.

For these same reasons, Scolnick has failed to demonstrate that no reasonable jury could find that he is liable under Section 10(b) for his April 2002 press release statement. The statement, he argues, merely expresses his genuine belief in Vioxx's safety based on a reasonable assessment of the available scientific data. The record contains sufficient evidence, however, to raise a genuine issue of fact as to the truth of his, and Merck's, confidence in the safety of Vioxx, as reflected in internal communications and the scientific data on which such an opinion was based.

Scolnick also maintains that neither the New York Times statement nor the Bloomberg News statement may form the basis of a Section 10(b) claim against him because Plaintiffs cannot demonstrate that he controlled the news articles containing the statements. Scolnick cites no authority for this argument. A Fourth Circuit case on which he relies is completely unpersuasive. In Raab v. General Physics Corporation, the Fourth Circuit Court of Appeals held that the plaintiff had failed to allege an actionable securities fraud violation against the corporate defendant because the subject statement, an analyst's report, was the independent statement of a third party. Raab v. General Physics Corp., 4 F.3d 286, 288 (4th Cir. 1993). The Raab court reasoned that, while the complaint alleged that the financial analyst reported information which the corporate defendant had "indicated," it did not in fact quote the corporate defendant's statement. Id. The court also noted that the complaint failed to plead who supplied the allegedly fraudulent information to the analyst. Id. It held that the securities laws "do not require the [defendant] company to police statements made by third parties for inaccuracies, even if the third party attributes the statement to [the defendant]." Id. Raab's reasoning is inapposite to the actionability of Scolnick's New York Times statement and Bloomberg News statement, which are both direct quotations of Scolnick's own assertions.

Scolnick is correct, however, that the Bloomberg News fails to provide the basis for a viable Section 10(b) claim on the grounds that no reasonable jury could find it misrepresents or omits a material fact. According to Plaintiffs, the statement is misleading in that Scolnick failed to disclose that, at the time, Merck was aware of facts indicating that Vioxx may increase CV risk. Plaintiffs also maintain that the statement is misleading because Merck did not ultimately conduct the CV outcomes study, as Scolnick represented it would. The Bloomberg News statement itself does not communicate false or incomplete information. Rather, as quoted in the

article, Scolnick states only that Merck would conduct further studies so that it could "100 percent sure" of Vioxx's safety and that, "[w]hatever the answer is in these studies, we will report it to the world." Though the article published these quotes in the context of reporting Merck's adherence to the naproxen hypothesis, it does not attribute to either Scolnick or Merck statements regarding Merck's view on the aspirin-like cardioprotective effect of naproxen. As such, the article provides no indication that, implicit in the quotation by Scolnick is his support for the naproxen hypothesis and/or his belief that the study will dispel, once and for all, any remaining doubt as to whether Vioxx is prothrombotic. Plaintiffs further argue that the misleading nature of the Bloomberg News statement is evident from the comments Scolnick made at the Annual Business Briefing of December 11, 2001, which provided the basis for the Bloomberg News article of the same date. As the Court noted earlier, the remarks Scolnick made at the meeting have not been pled as actionable statements in the Complaint and are not, therefore, at issue. The published quotations, moreover, reference further studies but do not discuss a CV outcomes clinical trial, and Merck's later decision not to conduct the VALOR trial does not render the statement misleading.

Second, Scolnick additionally contends that he is entitled to summary judgment because his October 25, 2000 sale of Merck stock does not constitute evidence of his scienter. The Third Circuit has held that while fraudulent intent may not be inferred merely from a company insider's sale of stock, "sales of company stock by insiders that are 'unusual in scope or timing . . . may support an inference of scienter.'" In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 277 (3d Cir. 2006). The Court need not reach this issue, as it has already determined that the record contains sufficient evidence, other than the stock sale, to give rise to a genuine issue of fact as to whether Scolnick acted with the requisite scienter. Even if no reasonable jury could

find that Scolnick's stock sale was sufficiently unusual to indicate that he intended to defraud investors, the Section 10(b) claim against him survives this motion for summary judgment.

B. Control Person Claim

Both Reicin and Scolnick, against whom Plaintiffs assert a control person claim pursuant to Section 20(a) of the Exchange Act, move for summary judgment on this claim on the grounds that Plaintiffs cannot as a matter of law establish either a predicate violation of the Exchange Act by Merck or the element of culpable participation. See Belmont v. MB Inv. Partners, Inc., 708 F.3d 470, 484 (3d Cir. 2013) (setting forth the three elements of a control person claim: an underlying Exchange Act violation by a controlled person or entity; defendant was a "controlling person;" and defendant was a "culpable participant" in the fraud). For the reasons discussed above, the record contains evidence demonstrating a genuine issue of fact as to whether Merck committed securities fraud in violation of Section 10(b) and Rule 10b-5. Thus, Defendants' argument that the control person claim must fail for lack of evidence of a predicate violation is unavailing. They have also failed to carry their burden of showing no genuine issue of fact as to the culpable participation of Scolnick and Reicin in the alleged Section 10(b) violation. Culpable participation refers to either knowing and substantial participation in the wrongdoing or inaction with the intent to further the fraud or prevent its discovery. Rochez Bros. v. Rhoades, 527 F.2d 880, 890 (3d Cir. 1975). For the reasons discussed, this Court has concluded that a reasonable jury could find that Reicin and Scolnick acted with scienter and therefore similarly concludes that a reasonable jury could find that Plaintiffs have established the culpable participation of these Defendants in Merck's underlying violation of the securities fraud laws. Accordingly, summary judgment on this claim is not warranted.

C. Insider Trading Claim

Scolnick moves for summary judgment on the insider trading claim, which is not asserted against the other Defendants. Scolnick argues that Plaintiff MPERS cannot proceed on its insider trading claim because it cannot establish that it engaged in contemporaneous trades with Scolnick. A claim for insider trading, or trading on non-public information, is governed by Section 20A of the Exchange Act. The provision provides a cause of action to "any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class." 15 U.S.C. 78t-1(a). The statute does not define the term "contemporaneous," nor has the Third Circuit issued a precedential opinion on its meaning. See In re Able Labs. Sec. Litig., No. 05-2681 (JAG), 2008 WL 1967509, at *26 (D.N.J. Mar. 24, 2008). However, Judge Joseph Greenaway, then sitting as a district judge in the District of New Jersey, noted in his Able Labs. opinion that "[v]arious district courts have seemed to define "contemporaneous" rather narrowly—that is, requiring trading to occur within a day." Id.

Scolnick does not deny that MPERS bought shares of Merck common stock on the same day, October 25, 2000, that he executed two sales of 600,600 shares and 200,000 shares, respectively. Nevertheless, he takes the position that MPERS cannot proceed to trial on its claim because the record shows that MPERS and Scolnick were not counterparties to the same transaction. In particular, Scolnick notes that MPERS made a single purchase of 15,600 shares at $86.00 per share whereas he made two separate sales at exactly $85.00 a share. Scolnick argues that because the contemporaneity requirement serves as a proxy for the traditional requirement of privity, its purpose and applicability is eviscerated by the transactions on which MPERS bases its claim. See Able Labs., 2008 WL 1967509, at *27 (consulting an unpublished

opinion from the Northern District of California, which explained that contemporaneousness developed as a proxy for contractual privity in view of the fact that "identifying the party in actual privity with the insider is virtually impossible in transactions occurring on an anonymous public market.") (quoting Buban v. O'Brien, No. 94-0331, 1994 WL 324093, at *3 (N.D. Cal. June 22, 1994). Scolnick cites no binding authority for such a restrictive definition of Section 20A's requirement that trades be contemporaneous. As such, the Court concludes that Scolnick has failed to demonstrate, as required by Rule 56(a), that there is no genuine issue of material fact on his insider trading claim.

Scolnick also argues that summary judgment on this claim is warranted on the grounds that MPERS has not sustained an injury-in-fact and therefore lacks standing. He asserts that, given that there is no dispute that MPERS sold its shares of Merck stock long before the date Plaintiffs allege the fraud was revealed, MPERS both bought and sold its shares at an allegedly inflated price, negating any claim of injury due to the alleged insider trading. This argument is based solely on the accounting method Scolnick urges this Court to apply, and Plaintiffs rebut with a counter-argument in favor of applying a different accounting method to evaluate loss. On the record before the Court, it is clear that MPERS has articulated a loss it claims to have sustained as a result of its October 25, 2000 purchase of Merck stock and Scolnick's conduct in violation of Section 20A. The evidence suffices to identify an injury-in-fact and confer standing upon MPERS to pursue the insider trading claim. In this case, whether it is entitled to recover for that alleged injury, and the proper valuation of such a loss, is a matter for the trier of fact.

D. Damages Model

Finally, Merck argues that summary judgment must be granted in its favor because the facts in the record do not support Plaintiffs' damages model. The model, proffered in the expert report of Dr. David Tabak, calculates the price drop in Merck stock attributable to the corrective disclosures, i.e., the amount by which Merck's stock price was inflated above its value had the market possessed truthful information about Vioxx, according to Plaintiffs' securities fraud allegations. To quantify the stock price decline attributable to the alleged fraud, the model ties the diminution in stock value to the impact that a disclosure of accurate information would have on Vioxx sales. According to the model, the inflated price of Merck stock before the corrective disclosure was made reflected the market's view that Vioxx was 100% commercially viable, and the uninflated price reflected the complete loss of sales, i.e., that had proper information been made public, or not disregarded by Merck, Vioxx would not have made it to market at all. Dr. Tabak's model provides for "other scenarios in which Vioxx would have remained on the market, but with lower sales, such as what would have occurred had there been a [product] warning." (Tabak Report, ¶ 140.)

Merck argues that the model is, essentially, hollow because it requires the jury to conclude that Vioxx should never have been marketed, been withdrawn from the market after VIGOR, or, alternatively, been relabeled with a "black box" warning so strong that it would have not been commercially viable. These conclusions, Merck further argues, cannot be made by a reasonable jury based on the factual record. Moreover, Merck maintains that while the model purports to be flexible, so as to allow damages to be measured based on evidence that a disclosure would have reduced but not eliminated sales, there is no evidence of either an

alternative corrective disclosure or the impact such disclosure would have on reducing sales of Vioxx.

Plaintiffs, in opposition, point to expert reports which they argue support their position regarding Vioxx's lack of commercial viability and thus, they maintain, would allow a jury to apply the Tabak damages model. Of course, given this Opinion's holding that the first alleged misrepresentation on which the Section 10(b) claim may proceed occurred on March, 27, 2000, Plaintiffs' contentions that Vioxx should never have come to market and related damages calculations no longer fit with the facts of this case. However, as Plaintiffs point out, Tabak's model provides for other scenarios, and they have proffered expert reports giving the opinion that, after VIGOR, Merck should have withdrawn Vioxx from the market (Zipes report) or given it a black box warning regarding the CV risks, which would have destroyed its commercial value (Bohigian report). While Merck may argue that Plaintiffs' expert reports are conclusory, unsupported by the record and unreliable, these objections to the expert opinions are best handled through a motion addressing the admissibility of the expert reports under Federal Rule of Evidence 702.

At this juncture, the Court concludes that Defendants have not met their burden under Federal Rule of Civil Procedure 56(a) of establishing that no reasonable jury could find in Plaintiffs' favor on damages, an essential element of their securities fraud claim. Accordingly, summary judgment on this ground is denied.

IV. CONCLUSION

For the foregoing reasons, the motion for summary judgment filed by Merck and Reicin and the motion for summary judgment filed by Scolnick will both be granted in part as to the Section 10(b) claim. Summary judgment in Defendants' favor will be entered insofar as the Section 10(b) claim is based on the pre-VIGOR statements, as defined in this Opinion, as well as the Bloomberg News statement. The remainder of their summary judgment motions will be denied.

An appropriate order will be filed.

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

Dated: May 13, 2015