**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| 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

This matter comes before the Court upon two motions to dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint ("Complaint") covering all Defendants in this case. The matter was opened by the motion to dismiss brought by Defendants Merck & Co., Inc., Raymond V. Gilmartin, Kenneth C. Frazier, Richard C. Henriques, Jr., Peter S. Kim, Judy C. Lewent, Alise S. Reicin, Lawrence A. Bossidy, William G. Bowen, Johnetta B. Cole, William B. Harrison, Jr., William N. Kelley, Heidi G. Miller, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, David Anstice, Richard T. Clark, Celia Colbert, Linda M. Distlerath, Caroline Dorsa, Bernard J. Kelley, Per G. H. Lofberg, Per Wold-Olsen and Lloyd C. Elam (hereinafter, these Defendants will be referred to collectively as "Merck") (docket item # 14). Defendant Dr. Edward M. Scolnick separately filed a motion to dismiss (docket item # 13). Upon being served, Defendant Niall Fitzgerald joined in Merck's motion to dismiss (docket item

#162) and therefore, will hereinafter be encompassed within the Court's collective reference to various defendants as "Merck." The motions seek dismissal on numerous grounds, including the running of the statutes of limitation. For the reasons that follow, the Court grants the motions and dismisses the Complaint as time-barred. Because the Court has determined that Plaintiffs' claims are untimely, the Court will not address the other arguments raised by Defendants in the motions to dismiss.

## I. BACKGROUND

This securities fraud class action concerns alleged misrepresentations and omissions made by Defendants about the safety profile of Merck's prescription drug VIOXX. Plaintiffs allege that Merck and Dr. Scolnick[1] concealed information that suggested or demonstrated that VIOXX significantly increased the risk of heart attack or other cardiovascular event and made misleading statements about the drug's safety. Plaintiffs, who purchased Merck securities during the time period from May 21, 1999 through October 29, 2004, allege that they bought the securities at prices that were artificially inflated due to Defendants' fraud. The earliest securities fraud complaint was filed on November 6, 2003.

### A. VIOXX Research and Safety Concerns

VIOXX, generically known as rofecoxib, is a nonsteroidal anti-inflammatory drug ("NSAID"). It was introduced to the market on May 21, 1999. In May 2001, the Federal Food

[1] Dr. Scolnick was Merck's Executive Vice President for Science and Technology and President for Merck Research Laboratories from the beginning of the Class Period (May 21, 1999) through December 31, 2002, when he retired. From January 1, 2003 through the end of the Class Period (October 29, 2004), Scolnick served as President Emeritus, Merck Research Laboratories.

and Drug Administration ("FDA") approved VIOXX for treating primary dysmenorrheal (severe menstrual cramps), managing acute pain in adults, and relieving symptoms relating to osteoarthritis. Merck promoted VIOXX as having a safety profile superior to other NSAIDs. Specifically, unlike traditional NSAIDs, which include aspirin, ibuprofen and naproxen, VIOXX did not cause serious gastrointestinal side effects. Whereas traditional NSAIDs operate by inhibiting two enzymes - cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2") - VIOXX selectively suppresses only COX-2 without affecting COX-1. This is significant because the suppression of COX-1 can lead to the deterioration of the stomach lining and gastrointestinal problems such as perforations and bleeds.

Merck continued to research, study and test VIOXX after its approval by the FDA and introduction to the market. One of these studies was Study 088, which the Court highlights because of its relevance to the facts on which the Court bases its decision on the motions to dismiss. In January 1999, Merck commenced Study 088, known as the VIOXX GI Outcomes Research ("VIGOR") study, to continue to examine VIOXX's gastrointestinal safety profile. Participants received either a daily dose of VIOXX at 50mg a day (twice the maximum recommended and approved chronic dose) or naproxen at 1000mg a day (a standard dose). Upon completion of the VIGOR study in March 2000, Merck made a public disclosure about the study in a March 27, 2000 press release. Among other things, the VIGOR study showed that thrombotic events, including myocardial infarction (heart attack), occurred in more patients in the VIOXX treatment group than in the naproxen treatment group. In relevant part, the March 27, 2000 press release stated that

> 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.

(Baron Decl., Ex. 5.) In other words, Merck took the position that the difference in thrombotic event rates between VIOXX and naproxen was due to a cardioprotective effect of naproxen (also known as the "naproxen hypothesis"). Significantly, according to the allegations made by Plaintiffs, Merck was aware that there was another explanation for the difference in thrombotic event rates in the VIGOR study's treatment groups, that is, that VIOXX had pro-thrombotic properties, or, in other words, that VIOXX increased the risk of a thrombotic event such as a heart attack.

On June 29, 2000, Merck submitted VIGOR data and analysis to the FDA. On February 8, 2001 the FDA's Arthritis Advisory Committee held a public hearing to discuss VIOXX's gastrointestinal and cardiovascular safety. Merck presented the naproxen hypothesis as the best explanation for the VIGOR results. The Committee found that VIGOR did not conclusively establish a link between VIOXX and cardiovascular risk. It also concluded, however, that Merck should include on the VIOXX label data about the higher incidence of cardiovascular events observed in the VIGOR study. A consultant to the Arthritis Advisory Committee on this issue and a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Steven Nissen, stated:

> Briefly, I think what I would say in the label is that there was an excess of cardiovascular events in comparison to naproxen, that it remains uncertain whether this was due to beneficial cardioprotective effects of naproxen or prothrombotic effects of the agent, and leave it at that, that basically we don't know the reason.

> We do know that there was a difference. That awareness should be made available to the prescriber and to the consumer, but without necessarily a final judgment as to the reasons for that difference.

(Id., Ex. 10, at 210:5-14.)

The VIGOR study initiated a public debate about the naproxen hypothesis versus the hypothesis that VIOXX increased cardiovascular risks. The issue received extensive coverage from the press, scientific publications, and financial analysts. In a November 23, 2000 article authored by both Merck and non-Merck scientists, the New England Journal of Medicine published the results of the VIGOR study; the article attributed the higher incidence of thrombotic events in VIOXX patients relative to naproxen patients to the purported cardioprotective effect of naproxen without raising the alternate explanation of increased risk due to VIOXX. (Id., Ex. 6.) Many financial analyst reports and articles published in scientific and medical literature as well as general news publications questioned Merck's interpretation of the VIGOR data. An April 27, 2000 report by Reuters cast doubt on "Merck's suggestion that naproxen conferred protection against heart attacks and strokes" and quoted Roche Holding, Ltd., a manufacturer of naproxen, as stating: "To our knowledge, naproxen does not prevent heart attack or stroke." (Id., Ex. 89). Following the February 8, 2001 FDA hearing, a February 9, 2001 article in USA Today stated that "[arthritis patients] should know that the blockbuster drug [VIOXX] might increase their risk of suffering a heart attack." (Id., Ex. 105.) On May 2, 2001, The New York Times also reported on the higher risk of heart attack for patients taking VIOXX. (Id., Ex. 106).

An article published in the August 22, 2001 Journal of the American Medical Association ("JAMA") reported results of a study of VIOXX and Celebrex conducted by the Cleveland

Clinic. It stated: "Current data suggest that the use of selective COX-2 inhibitors might lead to increased cardiovascular events." (Id., Ex. 3, at 958.) The article's authors argued that the data raised a "cautionary flag" about the risk of cardiovascular events with selective COX-2 inhibitors, such as VIOXX. (Id. at 954.) With regard to the VIGOR study, the article commented that "[t]he results of the VIGOR study can be explained by either a significant pro-thrombotic effect from rofecoxib or an antithrombotic effect from naproxen (or conceivably both)." (Id. at 957.) The JAMA article received extensive coverage in other publications, including mainstream news sources.

On the other hand, other news and analyst reports during the same 2000 to 2001 time period reinforced the naproxen hypothesis as the correct interpretation of the VIGOR data or minimized the concern raised about VIOXX's possible pro-thrombotic properties. Examples of such information include the following:

- April 12, 2000 Biotech Week article entitled "Merck & Co., Inc.: Preliminary Results of Gastrointestinal Outcomes Study Presented"

  > "Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and would not be expected to have similar effects. Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection."

- April 28, 2000 Dow Jones article

  > "[A]t least one analyst - and the company - said there's little to worry about. 'This whole thing has been overblown and taken out of context,' says Wall Street Journal All-Star analyst Jeff Chaffkin of PaineWebber. 'We had this data over four weeks ago. This is nothing new.'"

- May 1, 2000 Bernstein Research analyst report

> "We'd be shocked if [the] FDA gave this a second glance, much less re-labeled VIOXX to suggest greater risks of vascular events. It's not VIOXX increasing events, it's Naproxen reducing them."

- February 8, 2001 Bloomberg News article entitled "Merck Drug Should Note Heart Risk, Stomach Benefit, Panel Says"

> "Differences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx, said Nigel Harris, the [FDA Arthritis Advisory Committee] panel's chairman and the dean of the department of internal medicine at Morehouse School of Medicine."

- August 22, 2001 Credit Suisse First Boston analyst report

> "The JAMA researchers themselves point out several significant limitations in their study . . . We note that the VIGOR trial did not include low-dose aspirin, and that the control drug (naproxen) is known to possess a cardio-protective, anti-platelet effect. This makes it extremely difficult to determine whether the difference in cardiac events seen in VIGOR results from a naproxen 'benefit' or a Vioxx 'liability.'"

Merck did not remain silent in this public debate, and Plaintiffs highlight the consistent assurances Merck offered about the safety of its VIOXX product. All the while that certain media and financial analyst reports raised concern about whether VIOXX in fact increased the risk of heart attack, Merck disseminated positive information about the product, promoting its overall safety. In general, the statements attributed VIGOR data solely to the cardioprotectiveness of naproxen and/or discredited questions raised about the possibility that VIOXX is prothrombotic. Numerous press releases issued by Merck stated that VIOXX had an "excellent safety profile" and a "favorable cardiovascular safety profile." (Compl., ¶¶ 143, 190, 202-04.) In a June 13, 2001 press release announcing the findings of an analysis combining data

from 19 clinical studies, defendant Reicin, the Executive Director of Clinical Research at Merck, was quoted as stating that "results in the meta-analysis with VIOXX vs. naproxen are consistent with the ability of naproxen to block platelet aggregation, and, therefore, to act as an anti-platelet agent" – in other words, endorsing the naproxen hypothesis without disclosing that this explanation had not been confirmed and that the results may possibly be due to a prothrombotic effect of VIOXX. (Id., ¶ 206.) In anticipation of the August 22, 2001 article in JAMA, Merck commented that "we already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." (Id., ¶ 214).

**B. The FDA Warning Letter**

The FDA also entered, and fueled, the public discussion. On September 17, 2001, the FDA issued a Warning Letter to Merck concerning Merck's promotion of VIOXX. The letter admonished Merck for misrepresenting the safety profile of VIOXX, downplaying the cardiovascular findings of the VIGOR study, and explaining the results by offering the naproxen hypothesis as if it were based in fact. The letter stated:

> 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 increase 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 many have pro-thrombotic properties.
>
> * * *
>
> Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

(Baron Decl., Ex. 1 at 1-2.) In the Warning Letter, the FDA directed Merck to implement a corrective action plan, including ceasing the misleading promotion of VIOXX and issuing a letter to doctors to correct false information it had disseminated. (Id. at 7.)

The FDA Warning Letter was published on the FDA website on September 21, 2001. It received widespread media and analyst coverage. (Id., Ex. 58, 59.) Numerous articles appeared in well-known publications in late September and early October 2001. By way of example, the media reported as follows:

- September 24, 2001 Bloomberg News article entitled "Merck Misrepresents Safety of Vioxx, FDA Says in Warning Letter"

  > "The [FDA] cited Merck for minimizing 'potentially serious' findings in a study that showed heart attacks were significantly more common among patients who took Merck's drug than in patients who were treated with an older generic pain killer called naproxen."

- September 24, 2001 Reuters News article entitled "Merck Vioxx Promotions Said Misleading on Safety"

"U.S. Regulators have charged drug giant Merck and Co. Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." The article specifically references the September 17, 2001 FDA Warning Letter.

- September 25, 2001 USA Today article entitled "FDA Sends a Warning Letter to Maker of Vioxx Painkiller"

  "Merck's marketing efforts, aimed mainly at doctors, have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter' faxed Sept. 17 to Raymond Gilmartin, president and chief executive officer."

- September 25, 2001 Reuters News article entitled "Merck Slips After FDA Scolding on Vioxx Safety Claim"

  "Shares of Merck & Co. fell on Tuesday after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart attack from taking the medicine." The Reuters piece also discusses the study results reported in the August 22, 2001 JAMA article.

- September 25, 2001 Associated Press article entitled "FDA Says Merck Misleading on Vioxx Safety"

  "Merck has argued that Vioxx falsely looked risky because naproxen thins the blood much like aspirin does and thus protected against heart attacks . . . 'In fact, the situation is not at all clear,' the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy."

- September 25, 2001 Wall Street Journal article entitled "FDA Warns Merck for Vioxx Promotions"

  "The FDA said that the exact reason for the increased rate of heart problems [observed in Vioxx patients] isn't known, but that the Merck promotional campaign 'selectively' presented the hypothetical explanation that drugs used in comparisons with Vioxx help prevent heart problems – thus making Vioxx's rate of heart problems appear to be artificially inflated."

- September 26, 2001 New York Times article entitled "National Briefing Science and Health: U.S. Warns Merck About Marketing Arthritis Drug"

  "The Food and Drug Administration has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks."

The New York Times ran an article on October 9, 2001 regarding the possible cardiovascular risk posed by VIOXX. Although the article did make clear that VIOXX's propensity to increase the risk of heart attack had not been proven, it did report that the FDA had issued a warning letter requiring Merck to disclose the possibility of this risk. Importantly, the article quoted defendant Dr. Scolnick, the president of Merck Research Laboratories, regarding the results of the VIGOR study: "'There are two possible interpretations,' Dr. Scolnick said. 'Naproxen lowers the heart attack rate, or Vioxx raises it.'" (Rolnick Cert., Ex. A.) According to the article, Dr. Scolnick said that Merck had reviewed its data and concluded that "the likeliest interpretation of the data is that naproxen lowered lowered [sic] the thrombotic event rate," but that now, with new questions raised, none of the findings to date prove that the issue is fully resolved. (Id.)

**C. Other Lawsuits**

In the meantime, lawsuits concerning VIOXX were initiated against Merck. The first product liability class action was filed on May 29, 2001 in the United States District Court for the Eastern District of New York by attorney David Boies. The Complaint alleged that "[a]s demonstrated by Merck's own research, users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications, or combinations thereof . . . Nonetheless, Merck . . . [has] taken no affirmative steps to communicate this critical information

to class members." (Baron Decl., Ex. 33, ¶ 3.) Among other claims, the complaint asserted a failure to warn claim, which alleged that "Defendants failed to perform adequate testing prior to [the drug's] introduction in that adequate testing would have shown that patients taking Vioxx . . . had an increased risk of heart attacks than those patients taking more traditional non-prescription pain relief medication." (Id., ¶ 30.) It further averred that "the manufacturer[] knew or should have known that Vioxx . . . posed a greater risk to patients . . . ." (Id., ¶ 31.)

Additional suits were filed immediately after the publication of the FDA Warning Letter of September 17, 2001. One of these was a consumer fraud class action lawsuit filed in New Jersey state court on or about September 27, 2001. The New Jersey suit, captioned John Astin v. Merck & Co., Inc., concerned alleged misrepresentations and omissions of material fact by Merck regarding the pro-thrombotic properties of Vioxx. The Astin class action complaint pled for relief under New Jersey's Consumer Fraud Act and a common law fraud theory. It alleged as follows:

> Merck violated the Consumer Fraud Act . . . by engaging in unconscionable commercial practices, through deception, fraud, and making false promises and misrepresentations, including, but not limited to, the following:
>
> (1) Merck omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including, but not limited to, the risks of serious damage from cardiovascular problems. Furthermore, Merck has purposefully downplayed and /or understated the serious nature of the risks associated with Vioxx; . . .

(Id., Ex. 23, ¶ 32.) The Astin complaint relied on the FDA Warning Letter and on an August 22, 2001 Wall Street Journal article reporting on the study published in the JAMA article of the same date.

Another action, asserting both products liability and fraud claims, was filed in Utah state court in late September 2001 on behalf of 16 plaintiffs who alleged that Merck had intentionally and knowingly deceived users of Vioxx by concealing information about the possibility that Vioxx increases a patient's risk of suffering a heart attack or other cardiovascular event. The Utah action charged that "Evidence linking the subject drug formulations to significant edema, serious cardiovascular events, and death has been noted and reported in a large study (VIGOR) that was sponsored by Merck & Company, Inc. in 2000. These known material risks were not disclosed to or shared with Plaintiffs by Defendant." (Id., Ex. 24, ¶ 19.) The complaint relied on and quotes extensively from the FDA Warning Letter. It also quotes the August 22, 2001 JAMA article, an August 23, 2001 Wall Street Journal article concerning the JAMA article and a September 25, 2001 Associated Press piece reporting on the FDA Warning Letter.

**D. Withdrawal of VIOXX from the Market**

In September 2004, Merck was in the process of conducting another study of VIOXX to assess the effects of continuous treatment with VIOXX on the prevention and growth of recurrent colon polyps (known as the "APPROVe" study). An External Safety Monitoring Board ("ESMB") established to oversee APPROVe observed an increased rate of thrombotic events for patients taking VIOXX compared with patients taking a placebo and informed Merck that it was recommending that the study be stopped. On September 30, 2004, Merck voluntarily withdrew VIOXX from the market, stating that its decision was based on the data observed by the ESMB overseeing the APPROVe study and the availability of alternative therapies. (Id., Ex. 21, at 1.)

**E. VIOXX Securities Fraud Litigation**

On November 6, 2003, Plaintiffs filed the first VIOXX-related securities class action against Merck in the United States District Court for the Eastern District of Louisiana (the "Pringle action"). The Complaint alleged that Merck's failure to disclose material information about the cardiovascular risks of VIOXX had inflated the price of Merck stock and that plaintiff investors sustained a loss when the truth was revealed in October 2003, causing the stock price to decline. The Second Amended Complaint, filed on August 9, 2004, named Dr. Scolnick as a Defendant. Numerous additional suits were filed, in particular after Merck's withdrawal of VIOXX from the market. On February 23, 2005, the Judicial Panel on Multidistrict Litigation transferred all securities, shareholder derivative and ERISA actions relating to VIOXX to this Court.

The Complaint in the instant multi-districted securities class action contains six counts, asserting various claims under the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. 78a, et seq., (2000), and the Securities Act of 1933 ("Securities Act"), 15 U.S.C. 77a, et seq., (2000). Lead Plaintiffs Richard Reynolds, Steven LeVan, Jerome Haber and the Public Employees' Retirement System of Mississippi represent a class of plaintiffs consisting of the purchasers of Merck securities between May 21, 1999 and October 29, 2004. They claim that Merck made misrepresentations and omissions of material fact with respect to Vioxx's safety and cardiovascular risks, which deceived the investing public, artificially inflated the market price of Merck securities and caused the Class to purchase Merck securities at artificially inflated prices. Plaintiffs Rhoda Kanter and Park East, Inc. purchased shares of Merck common stock through the Merck Stock Investment Plan ("MSIP") pursuant to Merck's April 26, 2002 Registration

Statement and April 30, 2002 Prospectus. Kanter and Park East assert Securities Act claims on behalf of class members who purchased Merck stock through the MSIP.

Defendants move to dismiss the Complaint in its entirety with prejudice under Federal Rule of Civil Procedure 12(b)(6) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, et seq., (2000).

## II. LEGAL STANDARDS

### A. Standard of Review

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, the plaintiff is not entitled to relief. Oran v. Stafford, 226 F.3d 275, 279 (3d Cir. 2000). In other words, relief under Rule 12(b)(6) is warranted if it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations." Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Zynn v. O'Donnell, 688 F.2d 940, 941 (3d Cir. 1982). In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon those documents. See Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993).

The issue before the Court "is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236

(1974)). In this case, Defendants have moved under Rule 12(b)(6), in part on the grounds that Plaintiffs' claims are barred by the applicable statutes of limitations. To dismiss claims based on a statute of limitations defense, the time bar must be apparent on the face of the Complaint. Bethel v. Jendoco Contsr. Corp., 570 F.2d 1168, 1174 (3d Cir. 1978). Thus, Plaintiffs will not be entitled to pursue their claims if those claims are facially untimely.

**B. Applicable Statutes of Limitations**

Counts One through Three of the Complaint allege violations of sections 10(b), 20(a) and 20A of the Exchange Act, and Rule 10b-5 promulgated thereunder. 15 U.S.C. §§ 78j(b), 78t(a), 78t-1. Because this action was filed on November 6, 2003, after the enactment of the Sarbanes-Oxley Act on July 30, 2002, the limitations period set by Sarbanes-Oxley applies to Plaintiffs' Exchange Act claims. Lieberman v. Cambridge Partners, L.L.C., 432 F.3d 482, 489 (3d Cir. 2005). Sarbanes-Oxley extended the limitations period for private securities fraud claims under the Exchange Act to the earlier of two years after the discovery of the facts constituting the violation or five years after the violation. 28 U.S.C. § 1658(b). Prior to Sarbanes-Oxley, the applicable limitations periods were one and three years, respectively. 15 U.S.C. § 78i(e). While other circuits have held that Sarbanes-Oxley does not revive claims that were otherwise time-barred as of July 30, 2002, when the statute went into effect, see, e.g., In re ADC Telecomm., Inc. Sec. Litig., 409 F.3d 974 978 (8th Cir. 2005), the Court notes that Defendants have not argued that Plaintiffs' claims had expired by that date. The parties do not dispute that the applicable limitations period is the two-year/five-year structure under Sarbanes-Oxley.

The remaining three Counts of the Complaint assert violations of sections 11, 12(a)(2) and 15 of the Securities Act. 15 U.S.C. §§ 77k, 77l(a)(2), 77o. Section 13 of the Securities Act

provides the applicable statute of limitations. It states in relevant part:

> No action shall be maintained to enforce any liability created under section 77k [section 11] or 77l(a)(2) [ section 12(a)(2)] of this title unless brought within **one year** after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence.

15 U.S.C. § 77m (emphasis added). Although the statute refers only to causes of action under sections 11 and 12(a)(2), the Complaint's control person claim under section 15 is also governed by the one-year limitations period. Benak v. Alliance Capital Mgmt., L.P., 349 F.Supp.2d 882, 887 n.6 (D.N.J. 2004), aff'd, 435 F.3d 396 (3d Cir. 2006) (citing Hill v. Equitable Bank, Nat'l Assn., 599 F.Supp. 1062, 1078 (D. Del. 1984)).

**C. Accrual of Claims: Third Circuit's "Inquiry Notice" Standard**

Third Circuit jurisprudence requires this Court to apply an "inquiry notice" standard in determining when Plaintiffs' securities fraud claims accrued. Benak v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 400 (3d Cir. 2006); In re NAHC, 306 F.3d 1314, 1325 (3d Cir. 2002). Under this standard, plaintiffs need not have actual knowledge or know all of the details of the alleged fraud to trigger the limitations period. NAHC, 306 F.3d at 1325-26. Rather, inquiry notice exists when the plaintiffs discovered, or in the exercise of reasonable diligence should have discovered the general fraudulent scheme. Id. at 1326. It is at that point that the clock starts to run on the limitations period. Id.

The inquiry notice analysis is an objective one. The Court must evaluate whether sufficient information of wrongdoing or "storm warnings" of culpable activity existed such that a "reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning." Id. at 1325 (quoting Matthews v. Kidder, Peabody & Co.,

Inc., 260 F.3d 239, 252 (3d Cir. 2001)). Storm warnings may include "any financial, legal or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made." Id. at 1326, n. 5 (quoting Matthews, 260 F.3d at 252). Once storm warnings give rise to inquiry notice and trigger the limitations period, plaintiffs have an obligation to investigate the basis for their claims. Id. at 1326. The Court must charge them with constructive knowledge of all information discoverable through diligent research during that period. Id.

If a defendant succeeds in establishing inquiry notice, the burden then shifts to the plaintiffs to demonstrate that they were unable to discover their injuries despite the exercise of reasonable due diligence. Benak, 435 F.3d at 400. In other words, the plaintiffs must show that they undertook their duty to investigate the basis for their claims but nevertheless failed to discover information necessary to initiate a securities fraud action. Choosing not to investigate, however, is not a viable option, even in spite of protestations by plaintiffs that any efforts to acquire relevant information would have been difficult or fruitless. Id. at 401. "[I]f storm warnings existed, and the plaintiffs choose not to investigate, we will deem them on inquiry notice of their claims." Id. (quoting Matthews, 260 F.3d at 252 n. 16.)

## III. ANALYSIS

### A. Exchange Act Claims

Plaintiffs filed the initial securities fraud class action complaint in the Pringle action on November 6, 2003. Under the two-year limitations period applicable to their Exchange Act claims, Plaintiffs would have to have been on notice of their claims no earlier than November 6,

2001 for the claims to surmount the limitations bar. The evidence properly before the Court on this Rule 12(b)(6) motion - meaning the news articles, analyst reports, public documents and material referenced in the Complaint - demonstrates that Plaintiffs were on inquiry notice of their claims against Merck and Dr. Scolnick no later than October 9, 2001. On this date, the New York Times ran an article in which Dr. Scolnick acknowledged that Merck knew that the cardioprotective effect of naproxen was not proven and, further, that Merck admitted that VIOXX may raise the risk of heart attack or other thrombotic event. Moreover, by October 9, 2001, an overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX had accumulated in the public realm.

On September 21, 2001, the FDA published its Warning Letter of September 17, 2001 to Merck on its website.[2] The language of the Warning Letter is explicit. It charges Merck with engaging in deceptive and misleading conduct with regard to the safety profile of VIOXX. In particular, and in no uncertain terms, the FDA accuses Merck of misrepresentation by endorsing the naproxen hypothesis as fact, despite knowing that the cardioprotective effect of naproxen was merely hypothetical and unsupported by evidence. In addition, it publicly reprimands Merck for downplaying the potential safety problems with the drug by failing to disclose the known possibility that Vioxx increases the risk of myocardial infarction. The Warning Letter specifically references the VIGOR study and expresses the FDA's censure of the manner in which Merck has characterized the results of the study in its promotional activities and other public disclosures. Moreover, the accusations in the Warning Letter have particularly strong

[2] In addition to the fact that the September 17, 2001 FDA Warning Letter is a matter of public information, it is also properly considered by this Court on this motion to dismiss because it is specifically referenced in the Complaint. Burlington Coat Factory, 114 F.3d at 1426.

impact in light of the fact that they are leveled by Merck's principal regulator, which not only identifies specific improper conduct by Merck but also requires Merck to propose an action plan that would include ceasing misleading promotional activities and disseminating corrective messages.

A reasonable investor in Merck would have discovered this public, company-specific information and recognized it as a storm warning of fraud. Benak, 435 F.3d at 400-02 (discussing soundness of assumption in inquiry notice analysis that a direct investor in a company has motivation to stay informed about investment and would recognize information about company troubles as storm warning). The Warning Letter accused Merck of presenting as fact information that it knew was not. The wrongdoing charged in the Warning Letter is, moreover, the same alleged misconduct on which the securities fraud claims in this case are predicated. Indeed, the Court might arguably conclude that the FDA Warning Letter alone excited storm warnings sufficient to put Plaintiffs on inquiry notice of their claims against Merck.

The Court, however, need not make that conclusion, because the FDA Warning Letter was not issued in a vacuum of information. In fact, for months leading up to the issuance of the September 17, 2001 Warning Letter, numerous articles - many published in such mainstream news publications as The New York Times and USA Today - reported on the competing pro-thrombotic hypothesis to explain the VIGOR study results and the possibility that VIOXX in fact increased the risk of heart attack.[3] The media echoed doubts about the safety of Merck's

[3] Some of the articles considered by the Court herein in its inquiry notice analysis are referenced in the Complaint, such as the August 2001 JAMA article, while others are not. The Court may take judicial notice of public material such as newspaper articles and analyst reports

blockbuster drug. The August 22, 2001 JAMA article warned that data obtained from a VIOXX study indicated that its use "might lead to increased cardiovascular events." The JAMA article received press coverage and attention from financial analysts. Clearly, information raising at the very least doubts as to the safety profile of VIOXX accumulated in the public realm prior to the issuance of the Warning Letter. Moreover, a class action product liability suit was filed against Merck in the spring of 2001. The complaint in that case alleged that VIOXX was not safe, that patients taking the medication were subject to an increased risk of suffering a heart attack and that Merck's research bore this out. While not conclusive of knowing misrepresentations or omissions by Merck with regard to VIOXX, the product liability litigation must be recognized as a sign of the brewing storm. See Benak, 435 F.3d at 403 n. 20 (finding that the filing of a related lawsuit was a public event contributing to the existence of inquiry notice); see also In re Initial Public Offering Sec. Litig., 341 F.Supp.2d 328, 349 (S.D.N.Y. 2004) ("The filing of related lawsuits can suffice to put plaintiffs on inquiry notice, where the alleged fraud is similar").

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and consider them in applying the inquiry notice standard, even though the materials are extraneous to the Complaint. Benak, 435 F.3d at 400-01. In so holding, the Third Circuit reasoned as follows:

> The inquiry notice analysis is an objective one. Whether appellants read the articles or were aware of them is immaterial. They serve only to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true. "The Court may take judicial notice of newspaper articles for the fact of their publication without transforming the motion into one for summary judgment."

Id. at 401 n. 15 (quoting In re Merrill Lynch & Co. Research Reports Sec. Litig., 289 F.Supp.2d 416, 425 n. 15 (S.D.N.Y. 2003)) (citations omitted).

Public discussion of possible troubles at Merck continued, and it be may even be said intensified immediately following the publication of the Warning Letter. No fewer than eleven articles were published by such mainstream news services as Reuters, USA Today, The Wall Street Journal, The New York Times and The Associated Press between September 24, 2001 and October 9, 2001. The theme was consistent: the FDA "[has] charged drug giant Merck and Co., Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." (Baron Decl., Ex. 123.)

The last in this series of articles cited by Defendants - the October 9, 2001 New York Times article - presents a particularly probative indication of actionable misrepresentations by Merck concerning VIOXX. The article quotes defendant Dr. Scolnick - who was then president of Merck's research laboratories - as saying with regard to the VIGOR study results: "There are two possible interpretations. Naproxen lowers the heart attack rate, or Vioxx raises it." (Rolnick Cert., Ex. A.) Dr. Scolnick's statement admitted that Merck recognized the possibility that VIOXX may increase a user's risk of heart attack. It therefore represents a significant departure from Merck's company line as to the explanation for the VIGOR study results.

Add to this body of information readily available in the days and weeks after the FDA issued its Warning Letter the initiation of lawsuits related to VIOXX's alleged propensity for increasing a patent's risk of heart attack. The suits filed in New Jersey and Utah in late September 2001 are significant for two reasons. One, although they plead for relief under different legal theories than those at issue here - namely, under products liability and consumer fraud causes of action rather than securities fraud - the lawsuits are predicated upon the same

alleged wrongdoing as the allegations on which Plaintiffs base their securities fraud claims. The suits revolve around Merck's alleged misrepresentations and omissions regarding the known possibility that Vioxx increased a patient's risk of a thrombotic event. Two, the class action complaint in Astin, the New Jersey consumer fraud class action, and the 16-plaintiff complaint in the Utah state court action rely on such publicly available information as the JAMA article, the FDA Warning Letter and news stories reported by the Associated Press and the Wall Street Journal. The fact that the information available by the end of September 2001 would give those plaintiffs sufficient notice to file statutory and common law fraud claims as well as failure to warn claims against Merck reinforces the Court's conclusion that a reasonable investor of ordinary intelligence would have recognized, no later than early October 2001, warnings of troubles at Merck bearing on his or her investments.

The Court is not persuaded otherwise by Plaintiffs' argument that positive information about VIOXX disseminated by Merck in the months both before and after the publication of the FDA Warning Letter counterbalanced and offset any storm warnings. While the law of this Circuit does recognize that reassurances given by a company can dissipate storm warnings, an investor may not reasonably rely on words of comfort from management "when there are direct contradictions between the defendants' representations and the other materials available to plaintiffs regarding the possibility of fraud." In re Exxon Mobil Corp. Sec. Litig., 387 F.Supp.2d 407, 418 (D.N.J. 2005); see also Benak, 435 F.3d at 402 n. 16 ("Reassurances can dissipate apparent storm warnings 'if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns'") (quoting Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 169

(2d Cir. 2005)). While the mix of information prior to September 2001 included both negative information about possible safety problems with VIOXX, as well as the company's positive reassurances about the product and news and analyst reports echoing this off-setting information, the company reassurances ceased to be reliable upon the publication of the FDA Warning Letter. As discussed, the Warning Letter expressly charged Merck with misrepresenting the safety profile of VIOXX, misleading the public by presenting the naproxen hypothesis as the reason for the increased incidence of heart attacks in patients taking VIOXX in the VIGOR study and failing to disclose that the results may also be due to pro-thrombotic properties of VIOXX. A reasonable investor could not continue to rely on Merck's reassurances to allay his or her concerns in light of this public information.

Plaintiffs have tried to minimize the impact of the Warning Letter by arguing that their claims center on the contention that Merck, at the time it touted the naproxen hypothesis, actually knew that VIOXX increased the risk of heart attack. Plaintiffs, in fact, sought permission to submit supplementary briefing on the relative unimportance of the Warning Letter and the other lawsuits to the storm warning analysis. While the Court has read the untimely submission, it notes that the letter brief merely amplifies the argument raised at oral argument. To summarize, in Plaintiffs' view, public information such as the FDA Warning Letter, which castigated Merck for its misrepresentation of the safety profile of VIOXX by promoting the naproxen hypothesis without evidence to support it, did not put Plaintiffs on notice that Merck's fraud was more extensive, viz. actively promoting the naproxen hypothesis while knowing it was false. Plaintiffs thus argue that they did not have inquiry notice of Defendants' "true" more extensive fraud until,

at the earliest, Merck revealed information in October 2003 that the commercial performance and even viability of VIOXX were in jeopardy.

This argument is untenable. As noted earlier, inquiry notice exists when Plaintiffs discovered, or in the exercise of reasonable diligence should have discovered the general fraudulent scheme. NAHC, 306 F.3d at 1326. They need not have discovered every detail of the alleged fraud, nor need they have a thoroughly developed lawsuit ready to file at the moment at which inquiry notice arises. Id. at 1327. Plaintiffs' position that their claims did not accrue until the existence of fraud was a probability, as opposed to a possiblity, and that the "facts that give rise to inquiry notice must be sufficiently advanced and substantiated to enable the plaintiff to 'tie up any loose ends' before filing suit" (Pl. Br. at 58) is simply not supported by Third Circuit law. Their argument that fraudulent statements made after November 6, 2001 delay the running of the limitations period is likewise incorrect. This Court is not aware of any authority, nor has any been cited by Plaintiffs, in support of the contention that inquiry notice of fraud does not exist until corrective disclosures are made.

Here, by November 6, 2001, Plaintiffs were already on notice that the FDA had accused Merck of misrepresenting the safety profile of VIOXX by promoting a theory that had not been demonstrated by substantial evidence. In the Warning Letter, the FDA admonishes Merck by stating:

> 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.

The FDA focuses its criticism of Merck on Merck's knowing misrepresentation of Vioxx's safety profile:

> Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

Surely, this charge by the FDA against Merck, of making factual claims while knowing it does not have factual support for them, is not merely a "red flag" suggesting fraud. Rather, it is a direct and unequivocal accusation of fraud. Plaintiffs premise this lawsuit on Defendants' alleged knowing misrepresentation of the safety profile of VIOXX, that is, on the allegation that Merck promoted VIOXX as having a safety profile superior to traditional NSAIDs even though, according to Plaintiffs, it knew that VIOXX increased a user's risk of heart attack. It is prepostorous for Plaintiffs to argue that because they did not have a "smoking gun" that demonstrated that Defendants' misrepresentation was even more egregious than the Warning Letter charged, they were not on inquiry notice of a general fraudulent scheme regarding the safety of VIOXX.

Publication of the Warning Letter added to the available mix of information in a significant way, as there can be no doubt that in possession of this body of knowledge - including the press coverage which immediately followed - a reasonable investor of ordinary intelligence would identify the possibility that Merck had knowingly misrepresented material facts with

regard to VIOXX. Indeed, the torrent of publicity discussed above is more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm. Read in light of the accumulation of public information about Merck's misrepresentation of the safety profile of VIOXX, the New York Times article of October 9, 2001 leaves no doubt that by then, investors in Merck securities knew or should have known of the general fraudulent scheme perpetrated by Merck with regard to the safety of VIOXX. The article marks October 9, 2001 as the latest possible date on which Plaintiffs can be charged with inquiry notice of their fraud claims against Merck and Dr. Scolnick.

The reasoning and holding of the Third Circuit in Benak v. Alliance Capital Management compel this conclusion. Benak was a private securities fraud action brought not by a direct investor in a company against the company, but by mutual fund investors against the mutual fund and its advisers. One of the companies in which the subject fund invested its clients' money was Enron. The plaintiff investors asserted securities fraud claims, alleging that the fund's publicized claims of its investment strategies and companies in which it invested were materially misleading in light of the fund's continued investment in Enron despite the negative public information about Enron's financial state. Benak, 435 F.3d at 398-99. On the defendants' motion, the district court dismissed the Benak class action complaint on statute of limitations grounds. Applying the inquiry notice principles it articulated in NAHC, the Third Circuit Court of Appeals affirmed the dismissal. Id. at 404.

Of particular relevance to this case is the Benak court's acknowledgment of the difference between a direct investor and a mutual fund investor. In particular, for the purposes of the

inquiry notice analysis, the Court observed that whereas an investor who invests directly in a company would be charged with keeping abreast of information about the company, including its performance and possible troubles, a mutual fund investor stands in a disadvantaged position in terms of identifying information probative of problems affecting his or her investments. Id. at 402-03. The reason for the disadvantage is two-fold. First, a fund investor reasonably passes the responsibility for maintaining consistent knowledge of the condition of different companies on to the fund. Id. at 402. Second, a fund investor may have little idea at any one time in what securities his or her money is invested. Id. Contrasting the treatment of a direct investor and a mutual fund investor in the inquiry notice analysis, the Court reasoned as follows:

> Undergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of reasonable diligence, to file an adequately pled securities fraud complaint as of an earlier date. In the case of a direct investor - who one would assume has or can be deemed to have consistent knowledge of his or her securities holdings - the storm warning analysis becomes relatively simple. Upon reading news reports regarding the financial woes of a particular company and speculation regarding the management of that company, a direct investor immediately has reason for concern. Moreover, in being responsible for his or her own investments, a direct investor has greater motivation - and therefore, one would assume, be more likely - to stay informed. Upon receiving such information and inquiring further regarding the accuracy of that information, a direct investor - again, knowing the amount and nature of his or her holdings - could file suit almost immediately.

Id. at 401.

In short, in tweaking the inquiry notice analysis to fit the peculiarities of a mutual fund investor's potential securities fraud claims, the Third Circuit in Benak instructed that storm

warnings as to a direct investor's fraud claims will arise upon a much lower threshold of information than storm warnings surrounding a mutual fund investor's stake in a company. The Benak court then went on to conclude that, even upon the higher threshold of information required to put the mutual fund investor on inquiry notice, the standard had been met as to the Benak plaintiffs based on news articles about possible troubles at Enron, combined with the publicity given to Enron's bankruptcy filing, media accounts noting the mutual fund's holdings in Enron, and the earlier filing of a lawsuit predicated on related wrongdoing. Id. at 403. Because these storm warnings existed well before one year before the complaint was filed,[4] the Third Circuit concluded that the District Court had properly dismissed the complaint as time-barred.

In this case, of course, the Court deals with claims brought by direct investors in Merck. For the reasons discussed above, the abundant public information leading up to and immediately following the FDA Warning Letter - in addition to the Warning Letter itself - would give an investor in Merck reason for concern and charge him or her with the responsibility of conducting a diligent investigation. The latest accrual date that would permit the Court to conclude that Plaintiffs' Exchange Act claims are not precluded by the statute of limitations is November 6, 2001. Given that the FDA Warning Letter was published on September 21, 2001, and that it received a substantial amount of attention from the media and financial analysts immediately following its publication, the Court finds that it is clear that storm warnings of fraud by the

[4] The pre-Sarbanes-Oxley one-year statute of limitations under 15 U.S.C. § 78i(e) applied to the claims in Benak. Benak, 435 F.3d at 400.

company existed more than two years before this Complaint was filed.

Once the burden has been met by the defendants to demonstrate storm warnings, the burden shifts to the plaintiffs to show that they exercised reasonable due diligence but nevertheless were unable to discover their injuries. Plaintiffs here have not argued that they conducted a diligent investigation, and nothing in the Complaint demonstrates that they were unable to uncover pertinent information during the limitations period. Thus, "the knowledge they would have inquired through investigation is imputed to them." Benak, at 401. For the reasons discussed above, a reasonable investor would have discovered the basis for his fraud claims against Merck with respect to alleged misrepresentations about VIOXX within the two years following the storm warnings which existed before November 6, 2001.

Because the instant securities fraud action was filed over two years from the time that Plaintiffs were on inquiry notice of their claims, the Complaint's Exchange Act claims are barred by the applicable statute of limitations. Defendants' motion to dismiss must be granted, as Plaintiffs have failed to state a cause of action upon which this Court may order relief.

**B. Securities Act Claims**

Having concluded that Plaintiffs were on inquiry notice of their claims by early October 2001, the Court finds that Plaintiffs' Securities Act claims are also time-barred. The claims brought under the Securities Act relate to stock purchased through the MSIP pursuant to Merck's April 26, 2002 Registration Statement and April 30, 2002 Prospectus. It follows from the analysis in Section III.A of this Opinion that Plaintiffs were on inquiry notice of their Securities Act claims based on the allegedly false representations made in the April 2002 Registration

Statement and Prospectus immediately upon the issuance of these documents. Under the one-year statute of limitations applicable to Securities Act claims, these claims expired no later than April 30, 2003, months before this lawsuit was filed. Accordingly, Counts Three through Six of the Complaint must also be dismissed as time-barred.

## IV. CONCLUSION

For the foregoing reasons, the Court grants Defendants' motions to dismiss. The entire Complaint must be dismissed with prejudice as untimely. An appropriate form of Order will be filed.

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

Dated: April 12, 2007