PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 07-2431, 07-2432

IN RE: MERCK & CO., INC. SECURITIES,
DERIVATIVE & "ERISA" LITIGATION
(MDL No. 1658)

CONSOLIDATED SECURITIES LITIGATION

Richard Reynolds, Steven LeVan, Jerome Haber and The Public Employees' Retirement System of Mississippi, the Court-Appointed Lead Plaintiffs and Plaintiffs Union Asset Management Holding AG, Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherrie B. Knuth, Joseph S. Fisher, M.D., Naomi Raphael, Rhoda Kanter, Park East, Inc. and Marc Nathanson, on behalf of themselves and the proposed class of purchasers of Merck securities during the period between May 21, 1999 and October 29, 2004,

Appellants

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Nos. 05-cv-01151, 05-cv-02367)
District Judge: Honorable Stanley R. Chesler

Argued June 24, 2008

Before: SLOVITER, BARRY, and, ROTH
Circuit Judges

(Filed September 9, 2008)

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OPINION OF THE COURT

SLOVITER, Circuit Judge.

Appellants, purchasers of Merck & Co., Inc. stock, filed the first of several class action securities fraud complaints on November 6, 2003, alleging that the company and certain of its officers and directors (collectively, "Merck") misrepresented the safety profile and commercial viability of Vioxx, a pain reliever that was withdrawn from the market in September 2004 due to safety concerns. The District Court granted Merck's motion to dismiss the complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure, holding that Appellants were put on inquiry notice of the alleged fraud more than two years before they filed suit, and thus their claims were barred by the statute of limitations. Appellants argue that the District Court erred in finding as a matter of law that there was sufficient public information prior to November 6, 2001 to trigger Appellants' duty to investigate the alleged fraud. Because the District Court dismissed on the basis of the complaint, we must accept its allegations as true.[1]

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[1] The District Court took judicial notice of the various public documents submitted to it in connection with the motion to dismiss. Appellants do not challenge this decision on appeal and we see no reason to disturb it. "The inquiry notice analysis is an objective one. Whether appellants read the [documents] 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 [documents] were in fact true." Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 401 n.15 (3d Cir. 2006).

I.

Factual Background

In May 1999, the Food and Drug Administration ("FDA") approved Vioxx, a new drug introduced by the pharmaceutical company Merck. Vioxx is the brand name of rofecoxib, a nonsteroidal anti-inflammatory drug ("NSAID") used in the treatment of arthritis and other acute pain. Most NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: cyclooxygenase-1 ("COX-1"), which is associated with the maintenance of gastrointestinal ("GI") mucus and platelet aggregation, and cyclooxygenase-2 ("COX-2"), which is associated with the response to pain and inflammation. The inhibition of COX-1 leads to harmful GI side effects. Because Vioxx was designed to suppress COX-2 without affecting COX-1, Merck marketed Vioxx as possessing the beneficial effects of traditional NSAIDs but without the harmful GI side effects associated with those drugs. The market viewed Vioxx as a potential "blockbuster" drug for the company, App. at 469, and as its "savior," App. at 494. Merck repeatedly touted the safety profile, sales, and commercial prospects of the drug in press releases, public statements, and Securities and Exchange Commission ("SEC") filings throughout the class period.

A. Pre-FDA Approval and the VIGOR Study (1996 - March 2000)

Prior to the FDA's approval of Vioxx, officials at Merck were concerned that Vioxx could cause harmful cardiovascular ("CV") events, such as heart

attacks. Internal emails from 1996 and 1997 demonstrate that Merck employees were aware that there was "a substantial chance" and a "possibility" of CV events that could "kill [the] drug." App. at 496. In 1998, an unpublished internal Merck clinical trial entitled Study 090 revealed that Vioxx caused a greater incidence of CV events than a placebo or a different arthritis drug.[2]

In January 1999, Merck commenced the VIOXX Gastrointestinal Outcomes Research ("VIGOR") study, which compared Vioxx to naproxen, the active ingredient in brand-name pain relievers such as Aleve and Naprosyn.[3] Although the study showed that Vioxx had a GI safety profile superior to that of naproxen, it also showed that Vioxx users had a higher incidence of CV events than naproxen users. In a March 9, 2000 email, defendant Edward Scolnick, the President of Merck Research Laboratories, acknowledged the existence of CV events, commenting, "it is a shame but it is a low incidence and it is mechanism based as we worried it was." App. at 512.

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[2] The sources upon which Appellants rely in making these allegations were first made public in November 2004, approximately a year after Appellants filed their initial complaint. See Anna Wilde Mathews & Barbara Martinez, Warning Signs: E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage, Wall St. J., Nov. 1, 2004, at A1; 60 Minutes (CBS television broadcast Nov. 14, 2004) (transcript available on LexisNexis).

[3] See ALEVE FAQs, http://www.aleve.com/faqs.html#g21 (last visited July 25, 2008); Roche Pharmaceuticals in the U.S., Our Products, Naprosyn, http://www.rocheusa.com/products/naprosyn/ (last visited July 25, 2008).

Merck did not attempt to conceal the results of the VIGOR study. It made them public in a press release on March 27, 2000, that emphasized Vioxx's superior GI safety profile but also noted the incidence of CV events. Merck stated:

> [S]ignificantly 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.

App. at 765. The press release also stated that "[a]n 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." App. at 766.

The VIGOR study results were widely reported in the press, medical journals, and securities analyst reports. Market analysts and members of the press immediately understood that CV events could be a side effect of Vioxx. Nonetheless, many observers also took notice of Merck's hypothesis that naproxen lowered CV events (the "naproxen hypothesis"). The naproxen hypothesis attributed the results of the VIGOR study to the beneficial effects of naproxen's blocking of platelet aggregation rather than to the harmful effects of Vioxx in causing thromboembolic

events. The issue whether naproxen lowered the heart attack risk or Vioxx caused it was thus presented. While many analysts noted that the naproxen hypothesis was unproven, some also concluded that it was the most likely explanation for the increased CV events observed in the VIGOR study.

One representative article distributed by Reuters on April 27, 2000, quoted a Merck spokesman who acknowledged the "statistically significant" finding that patients of Vioxx had a higher rate of CV events, but suggested that this might be explained by a beneficial effect of naproxen. App. at 2287. In that same article, however, a spokesperson for the manufacturer of Naprosyn explained that the company had no knowledge that naproxen prevented heart attacks or strokes; similarly, an analyst for ABN Amro suggested that he was skeptical of Merck's explanation.

B. FDA AAC Hearing (February 8, 2001)

On February 8, 2001, the FDA's Arthritis Advisory Committee ("AAC") held a public hearing to consider Merck's request to include the positive GI results from the VIGOR study in its Vioxx labeling. Six days before that hearing, J.P. Morgan issued a research report summing up the state of knowledge about Vioxx after the VIGOR study. The report stated that the basic idea behind the naproxen hypothesis was "poorly proven," and that there was "no way to retrospectively slice the data to prove the NSAID benefit vs. Vioxx risk argument," although one existing theory "might support a 'Vioxx risk' hypothesis." App. at 2547. J.P. Morgan warned,

"[t]his is the type of clinical 'signal' that was ignored, and later haunted the FDA in recent drug recalls like Warner Lambert's Rezulin and Glaxo's Lotronex." App. at 2547.

During the AAC hearing, defendant Alise Reicin, Executive Director of Clinical Research at Merck Research Laboratories, explained to the panel, "when you review the results of VIGOR in isolation you don't know whether the imbalance of cardiovascular events was caused by a decrease in events on a platelet-inhibiting NSAID, naproxen, or an increase in events on a COX-2 selective inhibitor," i.e., Vioxx. App. at 995. She then suggested that naproxen was likely responsible for the difference in CV events observed in users of the two drugs. At the public portion of the hearing, the panel subsequently discussed whether to call for the inclusion of a warning in the Vioxx labeling stating that it was "uncertain" whether the CV events noticed in VIGOR were "due to beneficial cardioprotective effects of naproxen or prothrombotic effects of [Vioxx], and leave it at that, that basically we don't know the reason." App. at 1143.

Nonetheless, some press accounts reported that certain AAC panel members asserted that "[d]ifferences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx," App. at 2311, and that there was "some reassurance that what we see, in effect, is a protective effect of naproxen," App. at 2306. In subsequent coverage, many securities analysts reported that the hearing had benefited Merck and they continued to project substantial future revenues for Vioxx. However, at least one

investment firm issued a report stating, "our skepticism relating to naproxen having a cardioprotective effect is reinforced" by the AAC hearing. App. at 2703.

C. First Vioxx Product Liability Lawsuit (May 2001)

In May 2001, a product liability lawsuit was filed jointly against Merck and the makers of Celebrex, a rival COX-2 selective inhibitor. The complaint alleged that the pharmaceutical companies "have consistently marketed Vioxx and Celebrex as highly effective pain relief drugs for patients suffering from osteoarthritis," despite the fact that "Merck's own research" demonstrated that "users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications, or combinations thereof." App. at 1748. The plaintiffs sought "emergency notice to class members and revised patient warnings, in the form of additional medical labeling which is presently being considered by the FDA . . . ." App. at 1748.

D. JAMA Article (August 22, 2001)

On August 22, 2001, the Journal of the American Medical Association ("JAMA") reported the results of a study of Vioxx and Celebrex clinical trials. The JAMA article asserted that available data raised a "cautionary flag" about the risk of CV events associated with COX-2 inhibitors. App. at 748. It also stated that "[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events." App. at 752. The day before that article was published, Bloomberg News reported

the statement of a Merck scientist that "[w]e 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." App. at 539. The JAMA article garnered extensive coverage. Some securities analysts responding to the article on the date of its publication referred to the basic content of the article as "not new news," App. at 2749, and noted that the FDA "debated many of the same issues in February of this year," at the AAC panel hearing. App. at 2751.

The day after the JAMA article's publication, Merck issued a press release stating that it "stands behind the overall and cardiovascular safety profile . . . of VIOXX." App. at 540. Merck also sent "'Dear Doctor' letters to physicians throughout the country disparaging the article as 'not based on any new clinical study' and assuring the physicians that Merck 'stands behind the overall and cardiovascular safety profile' of VIOXX.'" App. at 540.

E. FDA Warning Letter (September 21, 2001)

On September 21, 2001, the FDA posted on its website a warning letter that its Division of Drug Marketing, Advertising, and Communications ("DDMAC") had sent to Merck four days earlier regarding its marketing and promotion of Vioxx. In the letter, the DDMAC stated that Merck's "promotional activities and materials" for the marketing of Vioxx were "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and

applicable regulations." App. at 713. The letter explained:

> You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [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.

App. at 713. The letter also directed Merck to issue "Dear Healthcare provider" letters "to correct false or misleading impressions and information." App. at 719.

The FDA warning letter received widespread coverage by the media and securities analysts. Although many media reports focused on the mere fact of the warning letter,[4] securities analysts tended to emphasize the impact the warning letter would likely have on the prospective Vioxx labeling changes (which were not forthcoming until April 2002),[5]

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[4] A few representative examples follow: Reuters -- "U.S. regulators have charged . . . Merck . . . with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." App. at 2353. Associated Press -- "Merck has argued that [the VIGOR study results make] Vioxx falsely look[] risky because naproxen thins the blood . . . and thus protect[s] against heart attacks. . . . 'In fact, the situation is not at all clear,' [according to] the FDA . . . ." App. at 2360. USA Today -- "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' . . . . So far this year, the FDA has sent drug companies fewer than a dozen warning letters, which the agency reserves for activities that raise significant public health concerns." App. at 2355. Wall Street Journal -- "Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks. . . . While the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year." App. at 2361.

[5] For example, a report issued by Lehman Brothers stated: "We do not believe this letter will be predictive of the FDA's actions on the pending Vioxx label change. . . . Warning letters of this nature are certainly not unusual and in fact almost a staple of the pharmaceutical industry today. . . . As pointed out in the FDA warning letter, DDMAC does not dispute Merck's claims." App. at 2765-66.

Merck's ongoing promotional efforts,[6] and Merck's position in the market.[7] A report issued by UBS Warburg explained, "[t]he FDA pointed out that there is no definitive study proving or disproving either conclusion [regarding the higher incidence of CV events associated with Vioxx in the VIGOR study]. . . . The FDA's position appears similar to our own, which is that the data available to date are simply not definitive." App. at 2768. Nonetheless, securities analysts were of one voice in their projections for Merck and Vioxx; analysts from CIBC World Markets, Credit Suisse First Boston ("CSFB"), Dain Rauscher, Lehman Brothers, UBS Warburg, SG Cowen, and Morgan Stanley all maintained their ratings for Merck stock at "buy" or "hold" and/or continued to project increased future revenues for Vioxx.

In the five days between September 20, 2001 and September 25, 2001, Merck's stock price declined

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[6] One report issued by Merrill Lynch stated: "The FDA issued a warning letter to Merck . . . [and] is looking for Merck to cease all violative promotional activities . . . . We do not see how this issue can be helpful to Merck in promoting Vioxx." App. at 2752.

[7] A Dain Rauscher report focused on Vioxx's position in the actual marketplace, i.e., the doctor's office: "We believe th[e FDA warning letter] is unlikely to significantly alter physicians' prescribing practices [because it] is likely that these issues are already common knowledge in the medical community . . . ." App. at 2762. Meanwhile, a CIBC World Markets report considered how the warning letter might impact Merck's stock price: "The FDA warning letter as well as a recent JAMA article raising concerns of cardiovascular risk will continue to pressure the stock, now trading close to its 52-week low." App. at 2755.

by $4.16, or 6.6%, closing at $59.11 on September 25. Reuters reported this drop on September 25, explaining that "[s]hares of Merck & Co. fell . . . 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." App. at 2357. By October 1, 2001, however, Merck's stock price had rebounded to $64.66, $1.39 higher than its closing price before the warning letter was made public just over a week earlier.

F. Additional Vioxx Lawsuits (September 27, 2001)

A consumer fraud lawsuit was filed against Merck on behalf of Vioxx users on September 27, 2001. A second product liability lawsuit and a personal injury lawsuit followed shortly thereafter. In articulating their allegations of fraud and misrepresentations by Merck to consumers and Vioxx users, the consumer fraud and product liability suits relied in large part on the JAMA article, the FDA warning letter, and various media reports concerning Vioxx.

G. New York Times Article (October 9, 2001)

On October 9, 2001, the New York Times published an article about COX-2 inhibitors entitled "The Doctor's World; For Pain Reliever, Questions of Risk Remain Unresolved." App. at 653. The article reported on "troubling questions about whether Vioxx may have an unexpected side effect -- a very slight increase in the risk of heart attack." App. at

653. However, the article explained that "[t]he risk is hypothesized, not proved," and that "leading arthritis specialists . . . say that they are not concerned and that they prescribe the drugs for patients who may have heart disease." App. at 653. The article noted that "[a]t issue is the subtle question of what counts as evidence," App. at 653, explaining that the risk that COX-2 inhibitors cause blood-clotting was originally posed as a theory a few years earlier by a scientist from the University of Pennsylvania.

The article addressed defendant Scolnick's statements at length. According to the article, Scolnick said that Merck "look[ed] specifically for excess heart attacks and strokes in" the VIGOR study and found a higher incidence in the patients taking Vioxx. App. at 654. "'There are two possible interpretations,' Dr. Scolnick said. 'Naproxen lowers the heart attack rate, or Vioxx raises it.'" App. at 654. The article went on, "while [Merck] announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills in comparison to Vioxx. It found no evidence that Vioxx increased the risk of heart attacks, Dr. Scolnick said." App. at 654. "He said that the company decided that 'the likeliest interpretation of the data is that naproxen lowered . . . the thrombotic event rate' . . . . He added that without the theoretical question raised by [the University of Pennsylvania scientist], 'no one would have a question remaining in their mind that their [sic] might be an additional interpretation.'" App. at 654. The article reported Scolnick as conceding that "none of the findings to date are enough to prove that the issue is fully resolved. That lack of proof is why

the F.D.A. demanded that Merck explain both sides of the hypothesis, telling doctors and patients that it is not known whether naproxen protects against heart attacks or Vioxx makes them more likely." App. at 654.

There was no significant movement in Merck's stock price following the publication of the New York Times article.

H. Vioxx's Labeling Modified to Include CV Risks (April 2002)

Merck was not required to include the risk of CV events in its labeling until April 2002. The labeling ultimately incorporating that information explained the VIGOR study results and stated, "the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX . . . as compared to patients treated with naproxen . . . . The significance of the cardiovascular findings . . . is unknown." App. at 553. This language was incorporated into the "precautions" section of the Vioxx labeling, rather than the "warnings" section. In a conference call discussing the labeling changes, a Merck spokesperson reiterated the company's "belief that the effect seen in VIGOR were [sic] the results of the anti-platelet effect of naproxen. . . . So, I think that's a position Merck has always had and now its [sic] quite clearly laid out in the labeling." App. at 559.

I. Falling Vioxx Sales and the Harvard Study (October 2003)

On October 22, 2003, Reuters published an article entitled "Merck to Cut 4,400 Jobs, posts Flat Earnings," in which it reported that Merck was "hurt by falling sales of arthritis medicine VIOXX and a paucity of profitable new drugs. . . . The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks . . . ." App. at 570. That day, Merck's stock price dropped from $48.91 to $45.72, down 6.5%.

On October 30, 2003, the Wall Street Journal published an article entitled "VIOXX Study Sees Heart-Attack Risk," which addressed a recent study by the Harvard-affiliated Brigham and Women's Hospital in Boston that found an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo (the "Harvard study"). App. at 571. According to the article, "[i]n the first 30 days, the researchers found, VIOXX was linked to a 39% increased heart-attack risk compared with Celebrex. Between 30 and 90 days, that increased relative risk was 37%." App. at 571. A researcher stated that this was "the best study to date" and that it "greatly substantiates our concerns about the cardiac side effects" of Vioxx. App. at 571.

Merck's stock price dropped below the S&P 500 Index during this time, and did not rise above that index during the remainder of the class period.

J. Merck Withdraws Vioxx From the Market (September 2004)

On September 30, 2004, Merck announced that it was withdrawing Vioxx from the market based on a new study showing an "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." App. at 584. Merck's stock price dropped more than $12 per share that day, to close at $33.00, down 27% from the previous day's close. Securities analysts expressed their surprise at the suddenness of Merck's action.

On November 1, 2004, the Wall Street Journal reported, "internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects." App. at 589. Merck's stock price dropped another 9.7% based on this news. The news, which was first published nearly a year after Appellants filed their complaint, prompted one securities analyst to remark, "new information indicates to us that the situation might not be as innocent as we thought. . . . We recommend that investors sell Merck shares." App. at 594.

II.

Procedural History

The first class action securities complaint initiating this lawsuit was filed on November 6, 2003, just weeks after the media reported the results of the Harvard study and declining Vioxx sales. After numerous nationwide class actions were

consolidated, Appellants filed a fourth amended consolidated class action complaint. The complaint alleged that "Defendants' statements and omissions during the Class Period materially misrepresented the safety and commercial viability of VIOXX," App. at 489, in violation of sections 11, 12(a)(2), and 15 of the Securities Act of 1933, sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder.

Merck moved to dismiss Appellants' claims on the grounds that they were time-barred and that Appellants had failed to state a claim. The District Court granted that motion on the basis that the claims were time-barred. In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig., 483 F. Supp. 2d 407, 425 (D.N.J. 2007).[8] Appellants timely filed a notice of appeal.

III.

Jurisdiction and Standard of Review

The District Court had jurisdiction over this action pursuant to section 22 of the Securities Act, 15 U.S.C. § 77v; section 27 of the Securities Exchange Act, 15 U.S.C. § 78aa; and 28 U.S.C. § 1331. We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review over the District Court's

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[8] The District Court did not address Merck's argument that the allegations contained in the fourth amended consolidated class action complaint failed to satisfy the heightened standards of the Private Securities Litigation Reform Act of 1995 for pleading scienter, and we do not express any opinion on this issue.

dismissal of Appellants' claims for failure to comply with the statute of limitations. DeBenedictis v. Merrill Lynch & Co., Inc., 492 F.3d 209, 215 (3d Cir. 2007). Because the District Court granted Merck's motion to dismiss, "[w]e must 'accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party.'" Id. (quoting Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989)). The dismissal must be upheld only "'if it appears to a certainty that no relief could be granted under any set of facts which could be proved.'" Id. (quoting D.P. Enters., Inc. v. Bucks County Cmty. Coll., 725 F.2d 943, 944 (3d Cir. 1984)).

IV.

Discussion

The relevant statutes each contain their own statute of limitations. A complaint alleging "fraud, deceit, manipulation, or contrivance" under the Securities Exchange Act "may be brought not later than the earlier of . . . 2 years after the discovery of the facts constituting the violation; or . . . 5 years after such violation." 28 U.S.C. § 1658(b). Claims under the Securities Act are subject to a shorter, one-year limitation period from the time of discovery, but in no event may be filed later than three years after the public offering or sale of the security. 15 U.S.C. § 77m. Thus, if Appellants knew of the basis for their claims prior to November 6, 2001, two years before the first securities complaint was filed, all of their claims are barred by the statute of limitations. See DeBenedictis, 492 F.3d at 216.

"Whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had 'sufficient information of possible wrongdoing to place them on 'inquiry notice' or to excite 'storm warnings' of culpable activity.'" Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 400 (3d Cir. 2006) (quoting In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1325 (3d Cir. 2002)). This is an objective question; thus, an investor is not on inquiry notice until a "'reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning.'" In re NAHC, 306 F.3d at 1325 (quoting Mathews v. Kidder, Peabody & Co., 260 F.3d 239, 252 (3d Cir. 2001)).

"If the existence of storm warnings is adequately established the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." DeBenedictis, 492 F.3d at 216 (citations, alterations, and internal quotation marks omitted). Here, the District Court held that Appellants were on inquiry notice of their claims no later than October 9, 2001, the date the New York Times published the article reporting that defendant 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." In re Merck, 483 F. Supp. 2d at 419. The Court also noted what it characterized as the "overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX [that] had accumulated in the public realm" by that

date, in particular, the FDA warning letter. Id. In concluding that sufficient storm warnings of fraud existed more than two years prior to the filing of Appellants' complaint, the District Court observed that Appellants' "position that their claims did not accrue until the existence of fraud was a probability, as opposed to a possibility . . . is simply not supported by Third Circuit law." Id. at 422. Finally, noting that Appellants had "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," the Court concluded that Appellants' claims were time-barred and granted Merck's motion to dismiss. Id. at 424.

A. Principles of Inquiry Notice

Before reviewing the District Court's decision, we must address an ambiguity in our inquiry notice jurisprudence. Appellants contend that the statute of limitations does not begin to run until there is sufficient evidence of probable, rather than possible, wrongdoing by the defendants. Predictably, Merck supports the latter standard, arguing that inquiry notice may be triggered by evidence of possible wrongdoing. Both formulations find support in this court's precedents. Compare DeBenedictis, 492 F.3d at 216 (Inquiry notice may be established by proof of "'financial, legal, or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.'") (quoting In re NAHC, 306 F.3d at 1326-27 n.5) (emphasis added), with Benak, 435 F.3d at 400 ("'Whether the plaintiffs . . . should have known of the basis for their claims depends on whether they

had "sufficient information of possible wrongdoing to place them on 'inquiry notice' . . . ."'") (quoting In re NAHC, 306 F.3d at 1325) (emphasis added). We therefore take this opportunity to clarify the standard for inquiry notice in this circuit.

Our first comprehensive discussion of the appropriate standard for inquiry notice took place in the context of a claim filed pursuant to the Racketeer Influenced and Corrupt Organizations Act ("RICO").[9] See Mathews, 260 F.3d at 241. In Mathews, investors in low-risk securities sued their broker after the securities had lost more than half their value, alleging that the broker misled them about the nature of the funds and charged excessive fees and commissions. We affirmed the district court's grant of summary judgment for the broker because the complaint was time-barred. Id. at 244. In analyzing whether plaintiffs' suit was filed before RICO's statute of limitations had run, we applied a two-pronged test derived from the inquiry notice standard other courts had applied in the context of securities fraud claims. Id. at 251-52.

First, we noted the requirement to make an objective inquiry into whether the defendant had met its burden "to show the existence of 'storm warnings.'" Id. at 252. We explained that storm warnings "may take numerous forms," such as "'any financial, legal or other data that would alert a

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[9] Quoting extensively from Mathews, we recently reiterated the inquiry notice standard for RICO claims in Cetel v. Kirwan Financial Group, Inc., 460 F.3d 494, 506-07 (3d Cir. 2006).

reasonable person to the probability that misleading statements or significant omissions had been made.'" Id. (quoting unpublished district court opinion).[10] Second, we described an inquiry, "both subjective and objective," into whether the plaintiffs had met their burden "to show that they exercised reasonable due diligence and yet were unable to discover their injuries." Id. We then noted our agreement with the Court of Appeals for the Seventh Circuit that courts should be "mindful of the dangers in adopting too broad an interpretation of inquiry notice." Id. at 253 (citing Law v. Medco Research, Inc. ("Medco II"), 113 F.3d 781, 786 (7th Cir. 1997); Fujisawa Pharm. Co. v. Kapoor, 115 F.3d 1332, 1335 (7th Cir. 1997)).

A year later, we applied this standard to claims pleaded under the federal securities laws. See In re NAHC, 306 F.3d at 1318. The shareholders' claims in that case arose from a health care provider's collapse after the federal government enacted regulations that negatively impacted the provider's long-term care services business. Id. at 1318-21. In formally adopting the inquiry notice standard for securities claims, we stated that "[w]hether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on

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[10] Immediately before using this language regarding a "probability" of fraud, we noted without criticism that the district court had also framed the first prong of the inquiry notice standard as "'whether the plaintiffs knew or should have known of the possibility of fraud ("storm warnings") . . . .'" Mathews, 260 F.3d at 251-52 (quoting unpublished district court opinion). Thus, there is no basis to conclude that we rejected the notion of a possibility standard at that time.

whether they had 'sufficient information of possible wrongdoing to place them on "inquiry notice" or to excite "storm warnings" of culpable activity.'"[11] Id. at 1325 (quoting Gruber v. Price Waterhouse, 697 F. Supp. 859, 864 (E.D. Pa. 1988)). We explained that "[p]laintiffs need not know all of the details or 'narrow aspects' of the alleged fraud to trigger the limitations period; instead, the period begins to run from 'the time at which plaintiff should have discovered the general fraudulent scheme.'" Id. at 1326 (quoting In re Prudential Ins. Co. Sales Practices Litig., 975 F. Supp. 584, 599 (D.N.J. 1997)).

In affirming the district court's dismissal of the plaintiffs' claim arising from the impact of the federal regulations on the defendants' long-term care services business, we held that a series of disclosures, which accompanied a drastic decline in the company's stock price, id. at 1319, and culminated with the defendants' announcement that they were writing off goodwill and selling their business for nominal consideration, put the plaintiffs on inquiry notice that previous valuations of goodwill had been inflated, id. at 1326-27. This holding was bolstered by the plaintiffs' admission that the market had written off that business even before the defendants' announcement. Id. at 1327.

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[11] In a footnote of the same opinion, however, we stated that inquiry notice could be established on the basis of "'data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.'" See In re NAHC, 306 F.3d at 1325-26 n.5 (quoting Mathews, 260 F.3d at 252).

More recently, in 2006, we considered whether a suit filed by mutual fund investors against fund advisors who had invested heavily in Enron was barred by the statute of limitations. Benak, 435 F.3d at 397. In our decision, we dispensed with the probability language altogether, instead holding that storm warnings could be triggered by "'sufficient information of possible wrongdoing . . . .'" Id. at 400 (quoting In re NAHC, 306 F.3d at 1325). Applying our inquiry notice standard to the facts of that case, we distinguished mutual fund investors from direct investors on the ground that mutual fund investors rely on an intermediary to learn about the companies in which they have invested. Id. at 401-02. Nonetheless, because the investors in Benak had access to media reports about their fund's large holdings in Enron after that company went bankrupt, we concluded that the plaintiffs were on inquiry notice of the fraud by the time the media reported the bankruptcy. Id. at 402-03.

Finally, in a case decided just last year, we considered investors' claims that Merrill Lynch misled them by failing to disclose that a certain class of mutual fund shares was "never a rational choice of investment for them and that Merrill brokers received larger commissions on sales of such shares." DeBenedictis, 492 F.3d at 210. Merrill argued that news articles, National Association of Securities Dealers ("NASD") press releases, and the mutual funds' registration statements put the class on inquiry notice more than two years before the complaint was filed and that it should therefore be dismissed as time-barred. Id. at 214. After quoting the "probability" language first used by the district

court in Mathews, we addressed each category of storm warnings alleged. We noted that Merrill's registration statements disclosed the fee structure for the different classes of shares, which allowed investors to determine the relative costs and benefits of the different shares, and the different commissions applying to those shares. Id. at 216-17. We further concluded that storm warnings existed because the news reports and press releases identified by the defendants revealed that many brokers had been disciplined by the NASD for recommending the very class of shares that undergirded the plaintiffs' claims. Id. at 217. Accordingly, we concluded that the plaintiffs' claims were time-barred.

As this review of our precedent makes clear, although we have occasionally stated that inquiry notice may be triggered by evidence alerting an investor to the probability of wrongdoing, we have just as often emphasized that inquiry notice may be triggered by sufficient information of possible wrongdoing. This implies that a probability, in the sense of a nearly certain likelihood, of wrongdoing is not necessary to trigger storm warnings in this circuit. Therefore, we reaffirm that "whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity." Benak, 435 F.3d at 400 (citations, alteration, and internal quotation marks omitted). In so holding, we note that the majority of courts of appeals to have addressed the question employ a possibility standard when evaluating the likelihood

of wrongdoing sufficient to constitute storm warnings. See, e.g., GO Computer, Inc. v. Microsoft Corp., 508 F.3d 170, 179 (4th Cir. 2007); Tello v. Dean Witter Reynolds, Inc., 494 F.3d 956, 970 (11th Cir. 2007); Wolinetz v. Berkshire Life Ins. Co., 361 F.3d 44, 48 (1st Cir. 2004); Ritchey v. Horner, 244 F.3d 635, 639 (8th Cir. 2001); Berry v. Valence Tech., Inc., 175 F.3d 699, 705 (9th Cir. 1999); Sterlin v. Biomune Sys., 154 F.3d 1191, 1196 (10th Cir. 1998); LaSalle v. Medco Research, Inc. ("Medco I"), 54 F.3d 443, 444 (7th Cir. 1995); Jensen v. Snellings, 841 F.2d 600, 607 (5th Cir. 1988). But see Newman v. Warnaco Group, Inc., 335 F.3d 187, 193 (2d Cir. 2003) ("The [existence of] fraud must be probable, not merely possible.").

Nonetheless, simply repeating the word "possibility" or "probability" with ever-increasing frequency and intensity (as both parties did in their briefs and at oral argument) is hardly useful. Rather, we review the information set forth by the parties with an eye toward the practical effect of drawing the inquiry notice line at a particular date. In this vein, we have emphasized that "[u]ndergirding 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." Benak, 435 F.3d at 401. Similarly, the Court of Appeals for the Seventh Circuit, which has also applied a possibility standard, see Medco I, 54 F.3d at 444, has reasoned that "[t]he facts constituting [inquiry] notice must be sufficiently probative of fraud–sufficiently advanced beyond the stage of a mere suspicion, sufficiently confirmed or

substantiated–not only to incite the victim to investigate but also to enable him to tie up any loose ends and complete the investigation in time to file a timely suit," Fujisawa, 115 F.3d at 1335. In other words, simply stating that a smattering of evidence hinted at the possibility of some type of fraud does not answer the question whether there was "sufficient information of possible wrongdoing . . . to excite storm warnings of culpable activity" under the securities laws. Benak, 435 F.3d at 400 (citations and internal quotation marks omitted) (emphasis added).

This concern is reenforced by the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b).[12] Surely, Congress did not envision a statute of limitations that would open the floodgates to a rush of premature securities litigation when its primary foray into this field in recent decades has been to deter poorly pleaded allegations of securities fraud. See DeBenedictis, 492 F.3d at 217-18 (noting that "'the level of particularity in pleading required by the PSLRA is such that inquiry notice can be established only where the triggering data "relates directly to the misrepresentations and omissions" alleged.'") (quoting Lentell v. Merrill Lynch & Co., 396 F.3d 161, 171 (2d Cir. 2005)); cf. Mathews, 260

[12] The PSLRA requires plaintiffs pleading securities fraud to "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading," 15 U.S.C. § 78u-4(b)(1), and to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," i.e., scienter, id. § 78u-4(b)(2).

F.3d at 253 (expressing concern about "a flood of untimely litigation" were we to "adopt[] too broad an interpretation of inquiry notice").

B. Basis of Appellants' Claims

Appellants argue that the District Court mischaracterized the gravamen of their fraud allegations, thereby undermining the Court's conclusion that Appellants were on inquiry notice of the alleged wrongdoing. We have repeatedly stated that the fundamental concern of our analysis is whether plaintiffs were "'on inquiry notice of the basis for [their] claims'" prior to the relevant date triggering the statute of limitations. Benak, 435 F.3d at 400 (quoting In re NAHC, 306 F.3d at 1325). Therefore, we must carefully scrutinize the District Court's characterization of the basis for Appellants' claims and consider how this characterization affected the Court's inquiry notice analysis.

First, Appellants contend that the Court mischaracterized the basis for their claims by focusing on alleged misrepresentations about Vioxx's safety profile. In concluding that sufficient storm warnings existed to put Appellants on inquiry notice, the District Court considered the "overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX [that] had accumulated in the public realm" by October 9, 2001. In re Merck, 483 F. Supp. 2d at 419. Appellants argue that the true nature of their claims is that Vioxx "was so dangerous that it lacked any meaningful commercial prospects, or that [Merck's] representations in this regard were materially false and misleading when made . . . ." Appellant's Br. at

35. The difficulty with this contention is that Merck's representations about Vioxx's commercial viability are not unrelated to the company's representations about the drug's safety profile. If public information undermined Merck's representations about Vioxx's safety, a reasonable investor would also likely see such information as undermining Merck's representations about Vioxx's commercial viability. Indeed, some professional investors connected concerns about the safety of COX-2 inhibitors to their commercial viability.

Nonetheless, the fact that many securities analysts continued to maintain strong growth ratings for Vioxx at the same time that its safety was being questioned is certainly relevant to whether such questions constituted sufficient information of possible wrongdoing to trigger storm warnings. Even though there were analysts who connected Vioxx's safety to its commercial viability, it appears that they were not so worried about Vioxx's safety after the FDA warning letter was made public that they felt it necessary to retract their opinions about Vioxx's future profitability or Merck's market position.[13] In any event, Appellants argue that even

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[13] A September 25, 2001 report by a CSFB analyst illustrates the interrelatedness of the two propositions: "Recent prescription trends have indicated that adverse publicity and cardiovascular concerns have contributed to erosion in Vioxx (as well as Celebrex) market share within the collective COX-2/NSAID market." App. at 2757. On the other hand, the same CSFB report also "project[ed] Vioxx revenues will increase 42% year over year to $3.06 billion for 2001, with growth moderating to the +14% level in 2002 to $3.49 billion. We maintain our Buy rating." App. at 2757.

if their claims are properly characterized as alleging misrepresentations about Vioxx's safety, the District Court misinterpreted their claims in another respect.

Appellants contend that their complaint challenges the veracity of Merck's statements of opinion and belief regarding the naproxen hypothesis whereas the District Court analyzed whether Merck misrepresented the fact that the results of the VIGOR study could support multiple hypotheses (i.e., that naproxen lowers the risk of CV events or that Vioxx raises that risk). Thus, they argue that the District Court mischaracterized their claims by considering whether there were storm warnings that put them on notice of a fraud different from that which they have asserted in their complaint.

We have explained that for "misrepresentations in an opinion" or belief to be actionable, plaintiffs must show that the statement was "'issued without a genuine belief or reasonable basis' . . . ." Herskowitz v. Nutri/System, Inc., 857 F.2d 179, 185 (3d Cir. 1988) (quoting Eisenberg v. Gagnon, 766 F.2d 770, 776 (3d Cir. 1985)); accord Va. Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1095 (1991) ("A statement of belief may be open to objection . . . as a misstatement of the psychological fact of the speaker's belief in what he says."). Thus, to trigger "storm warnings of culpable activity," Benak, 435 F.3d at 400 (citations and internal quotation marks omitted), in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, i.e., that they did not hold those opinions or beliefs in earnest. Appellants' theory in the complaint is that Merck's statements

about the validity of the naproxen hypothesis were falsely-held statements of opinion or belief and that there was no information available to investors prior to November 6, 2001 that would have led them to suspect that such statements were not held in earnest. The District Court rejected this argument, concluding that "[i]t is prepost[e]rous for Plaintiffs to argue that because they did not have a 'smoking gun' that demonstrated that Defendants' misrepresentation was even more egregious than the [FDA] Warning Letter charged, they were not on inquiry notice of a general fraudulent scheme regarding the safety of VIOXX." In re Merck, 483 F. Supp. 2d at 422-23. We disagree.

It is true that "[p]laintiffs cannot avoid the time bar simply by claiming they lacked knowledge of the details or narrow aspects of the alleged fraud. Rather, the clock starts when they should have discovered the general fraudulent scheme." Benak, 435 F.3d at 400 (citations and internal quotation marks omitted). The "fraudulent scheme" referred to must be one "in connection with the purchase or sale of any security . . . ." 15 U.S.C. § 78j(b). Appellants have brought a securities fraud action, not a consumer fraud action, against Merck. See Gavin v. AT & T Corp., 464 F.3d 634, 640 (7th Cir. 2006) (recognizing that securities fraud suits and consumer fraud suits are not interchangeable); cf. Marine Bank v. Weaver, 455 U.S. 551, 556 (1982) ("Congress, in enacting the securities laws, did not intend to provide a broad federal remedy for all fraud."). Thus, the fact that the FDA sent a letter to Merck about its possible misrepresentations in connection with its promotion of Vioxx to health care professionals

would not have provided a storm warning unless it put Appellants on inquiry notice of actionable misrepresentations under the securities laws. See DeBenedictis, 492 F.3d at 218 (finding storm warning where disclosure was "directly applicable to the representations or omissions" challenged by plaintiffs). The asserted basis of Appellants' claims is that Merck defrauded investors by proposing and reasserting the naproxen hypothesis at the same time that it knew the hypothesis was false. We must analyze the existence of storm warnings relative to that allegation in order to determine whether Appellants were on inquiry notice of the alleged fraud.

C. Existence of Storm Warnings

Because the District Court believed that "[t]he wrongdoing charged in the [FDA] Warning Letter is . . . the same alleged misconduct on which the securities fraud claims in this case are predicated," the Court asserted that it "might arguably conclude that the FDA Warning Letter alone excited storm warnings sufficient to put Plaintiffs on inquiry notice of their claims against Merck," but it decided that it "need not make that conclusion, because the FDA Warning Letter was not issued in a vacuum of information." In re Merck, 483 F. Supp. 2d at 419. The Court then took notice of the JAMA article, the lawsuits filed against Merck in 2001, and various articles discussing competing explanations for the results of the VIGOR study. Id. at 419-21. The Court reasoned that the New York Times article following the FDA warning letter was especially probative because Scolnick "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." Id. at 420. The Court then rejected Appellants' argument that positive information issued by Merck during this period dissipated any storm warnings. Id. at 421.

Appellants argue that to the extent the disclosures identified by Merck might be seen as triggering storm warnings, such storm warnings were dissipated by Merck's reassuring statements,[14] and are undermined by the failure of the identified disclosures to have any significant impact on Merck's stock price or the projections of securities analysts covering Merck. Merck argues that stock price movement is irrelevant to the inquiry notice analysis. We cannot agree. Our past inquiry notice decisions have taken into account the market reaction to disclosures that purportedly constitute storm warnings. See, e.g., In re NAHC, 306 F.3d at 1319 (discussing drastic decline in stock price accompanying disclosures in period leading up to date of inquiry notice); cf. Benak, 435 F.3d at 403

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[14] We have recognized that "reassurances can dissipate apparent storm warnings if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns." Benak, 435 F.3d at 402 n.16 (citation, alteration, and internal quotation marks omitted). "'Whether reassuring statements justify reasonable reliance that apparent storm warnings have dissipated will depend in large part on how significant the company's disclosed problems are, how likely they are of a recurring nature, and how substantial are the "reassuring" steps announced to avoid their recurrence.'" DeBenedictis, 492 F.3d at 218 (quoting LC Capital Partners, LP v. Frontier Ins. Group, Inc., 318 F.3d 148, 155 (2d Cir. 2003)).

(noting that Enron's collapse and subsequent bankruptcy triggered inquiry notice); Mathews, 260 F.3d at 254 (explaining that 30% drop in funds' net asset values and 60% decline in distributions triggered inquiry notice). In Mathews, we explained that "in most securities fraud actions, the plaintiffs' [losses] are inextricably intertwined with the defendant's misrepresentations. Discovery of one leads almost immediately to discovery of the other." Mathews, 260 F.3d at 251. Similarly, in the context of materiality, we have stated that in "an efficient market, 'information important to reasonable investors . . . is immediately incorporated into the stock price.'" Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1425 (3d Cir. 1997)). "If the disclosure of certain information has no effect on stock prices, it follows that the information disclosed was immaterial as a matter of law." In re NAHC, 306 F.3d at 1330 (citing In re Burlington Coat Factory, 114 F.3d at 1425).

Because information that is material to reasonable investors is immediately incorporated into the stock price, the effect of a purported storm warning on the market, while insufficient on its own to compel the conclusion that inquiry notice has not been triggered, is, contrary to Merck's position, relevant to our inquiry. See Newman, 335 F.3d at 195 (asserting that the court's "holding is further supported by the fact that [defendant]'s stock price did not have any significant movement following" the identified disclosure); Berry, 175 F.3d at 705 (concluding that the lack of significant stock

movement "bolster[ed]" the conclusion that inquiry notice had not been triggered).

The District Court (and Merck on this appeal) emphasized five classes of information, each of which was disclosed on or before October 9, 2001, which purportedly triggered storm warnings: (1) articles and reports commenting on the hypothetical explanations for the results of the VIGOR study; (2) the JAMA article, which asserted that available data (i.e., VIGOR and a Celebrex study) raised a "cautionary flag" about the risk of CV events in COX-2 inhibitors, App. at 748; (3) the FDA warning letter, which charged Merck with "engag[ing] in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx," App. at 713; (4) the consumer fraud, product liability, and personal injury lawsuits filed against Merck throughout 2001; and (5) the New York Times article, in which Scolnick stated there were "two possible interpretations" for the VIGOR results, App. at 654. Because the disclosures in each of these categories ultimately arise from the results of the VIGOR study, we briefly recap the details of the study.

VIGOR compared Vioxx to naproxen in the hopes of establishing that Vioxx had a better GI profile than traditional NSAIDs. Although those hopes were realized, Merck also learned, and subsequently notified the public, that "significantly fewer thromboembolic events were observed in patients taking naproxen" than patients taking Vioxx. App. at 765. Merck suggested that naproxen's

effect on platelet aggregation was responsible for this difference, but conceded that this hypothetical effect "had not been observed previously in any clinical studies . . . ." App. at 765. Merck also stated that all other Vioxx trials "showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs." App. at 766.

Securities analysts and the press duly reported the results of VIGOR and the naproxen hypothesis. For instance, an article published in Bloomberg News a month after the VIGOR results were released reiterated Merck's hypothesis about naproxen's effect on platelet aggregation, but noted that "[n]aproxen doesn't have documented protective effects on the heart," and quoted an analyst who stated, "that Vioxx increases cardiac risk . . . may be true, but it is far too soon to make that kind of judgment." App. at 2292. Similarly, a J.P. Morgan report from April 2000 noted the intuitive appeal of the theory that "the thromboembolic event issue is an 'NSAID-issue,'" but explained that the "theoretical cardiovascular protective benefits of Naprosyn . . . have not been clinically proven . . . ." App. at 2376. In another article, a spokesperson for the makers of Naprosyn stated, "[t]o our knowledge, naproxen does not prevent heart attack or stroke . . . ." App. at 2288. In our view, this category of disclosures does not constitute storm warnings that Merck misrepresented Vioxx's safety profile to investors in a manner that might give rise to a securities fraud claim. On the contrary, securities analysts and the press recognized the naproxen hypothesis for what it was, an unproven hypothesis,

and recognized that there was an alternative hypothesis, "that Vioxx increases cardiac risk . . . ." App. at 2292.

Shortly before the AAC hearing, during which the FDA considered how Vioxx's labeling should be modified to incorporate the results of the VIGOR study, a J.P. Morgan research report described the effect of NSAIDs such as naproxen on CV events as "poorly proven" and explained that there was "no way to retrospectively slice the data to prove the NSAID benefit vs. Vioxx risk argument . . . ." App. at 2547. At that hearing, defendant Reicin, the Executive Director of Clinical Research at Merck Research Laboratories, who argued in support of the naproxen hypothesis, admitted at the outset that the explanation for the results of the VIGOR study was uncertain. The first Vioxx product liability lawsuit (which, incidentally, charged the makers of Celebrex with identical wrongdoing) followed shortly thereafter, seeking "additional medical labeling which is presently being considered by the FDA [in conjunction with the AAC hearing.]" App. at 1748. Of course, investors, unlike Vioxx patients, were presumed to be aware of the publicized outcomes of research studies, such as VIGOR, which underlay the allegations of that product liability lawsuit. See Benak, 435 F.3d at 401 (explaining that "a direct investor . . . can be deemed to have consistent knowledge of his or her securities holdings").

The JAMA article evaluated Vioxx and Celebrex, both COX-2 selective inhibitors, together; its findings were not limited to Vioxx. The article concluded, based in part on VIGOR, that "[c]urrent data would suggest that use of selective COX-2 inhibitors might

lead to increased cardiovascular events." App. at 752. Of course, this is simply the alternative to the naproxen hypothesis. The JAMA article did not present any data that would suggest that Merck did not have reason to propose that hypothesis. Accordingly, it is of little surprise that a Deutsche Banc securities analyst described the types of questions raised in the JAMA article as "not new news . . . ." App. at 2749. Moreover, Merck issued reassuring statements the day before and the day after the article was published. Again, we are of the view that the JAMA article, taken on its own, did not constitute sufficient information of possible wrongdoing under the securities laws so as to raise a storm warning of culpable activity under the securities laws.

The FDA warning letter demands more scrutiny. In analyzing the effect of that letter through the prism of inquiry notice, we must not lose focus of the nature of the allegations in the letter and the scope of the FDA's regulatory authority. The FDA targeted Merck's "promotional campaign for Vioxx," App. at 713, under its authority to regulate prescription drug advertisements, see 21 U.S.C. § 352(n); see generally Pa. Employees Benefit Trust Fund v. Zeneca Inc., 499 F.3d 239, 248-49 (3d Cir. 2007) (discussing the FDA's authority over prescription drug advertising). The letter focused on three distinct components of the promotional campaign that the FDA found of concern: (1) six promotional audio conferences, presumably aimed at health care professionals such as doctors and pharmacists; (2) a press release dated May 22, 2001 entitled "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," App. at 718;

and (3) oral representations made by Merck sales representatives, again, presumably to health care professionals. The FDA chastised Merck's promotional campaign for "discount[ing] 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" naproxen, and "selectively present[ing]" the naproxen hypothesis as the reason for the incidence of increased CV events. App. at 713. The FDA stated that Merck's promotional campaign "fail[ed] to disclose that [its] explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have prothrombotic properties." App. at 713. For a number of reasons, we are hesitant to conclude that the FDA warning letter was sufficient to trigger inquiry notice.

To begin with, the FDA was acting as a regulator of drug advertising, rather than as a regulator of the securities markets. Thus, contrary to Merck's contention at oral argument, the FDA's actions are hardly analogous to allegations of accounting fraud issued by the SEC, which regulates the securities markets. Indeed, the FDA's drug advertising regulations and the securities laws provide wholly different standards with respect to what constitutes a misrepresentation. FDA regulations provide that advertisements must not be "lacking in fair balance," 21 C.F.R. § 202.1(e)(6), and prohibit advertisements that "[c]ontain[] a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience . . . or

otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated," id. § 202.1(e)(6)(iv). In contrast, under the securities laws, "a fact or omission is material only if 'there is a substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered the "total mix" of information' available to the investor." In re NAHC, 306 F.3d at 1330 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)).

Second, the FDA's description of the truth about the VIGOR study is quite similar to the evidence that Merck had long acknowledged and which the market had incorporated. Specifically, the FDA stated that the naproxen hypothesis "is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties." App. at 713. This information is implicit in Merck's long-standing admission that the posited anti-coagulant effect of naproxen "on [CV] events had not been observed previously in any clinical studies for naproxen." App. at 765. On the basis of Merck's public announcements, securities analysts discussed the existence of "a 'Vioxx risk' hypothesis" over seven months before the FDA warning letter was issued. App. at 2547. Indeed, the FDA did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis; rather, the agency simply directed Merck to be more clear about the widely known alternative hypothesis in its dealings with health care professionals and, presumably, consumers.

Third, two of the three components of the promotional campaign subject to the FDA's reprimand consisted of statements made to health care professionals in the course of targeted audio conferences and personal conversations. The third component of the promotional campaign targeted by the FDA was the press release, but that press release merely repeated the same information that was first contained in the VIGOR press release, i.e., "significantly fewer heart attacks were observed in patients taking naproxen . . . compared to the group taking Vioxx," "the VIGOR finding is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1," "[t]his is the first time this effect of naproxen on cardiovascular events has been observed in a clinical study," and "[o]ther potential explanations" for the results were possible. Press Release, Merck & Co., Inc., Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx(R) (May 22, 2001) (available on PR Newswire and LexisNexis).

Finally, we consider the effect the FDA warning letter had on the market. Merck's stock price dipped slightly following the disclosure of the FDA warning letter before closing higher than it did before that disclosure just a week and a half later. Although the lack of significant movement in Merck's stock price following the FDA warning letter is not conclusive, it supports a conclusion that the letter did not constitute a sufficient suggestion of securities fraud to trigger a storm warning of culpable activity under the securities laws. See, e.g., Berry, 175 F.3d at 705 (asserting that the "negligible impact" of an alleged storm warning on defendant's stock price bolstered

conclusion that inquiry notice was not triggered). This conclusion is also supported by the fact that more than a half-dozen securities analysts continued to maintain their ratings for Merck stock and/or project increased future revenues for Vioxx after the warning letter was made public.

Merck also emphasizes the three additional lawsuits filed after the FDA warning letter. Of course, none of these lawsuits alleged securities fraud. Rather, they alleged consumer fraud, product liability, and personal injury claims. The claims in those lawsuits alleged that Merck failed to provide publicly available information to Vioxx consumers, rather than to Merck investors. Cf. In re Ames Dep't Stores, Inc. Note Litig., 991 F.2d 968, 980 (2d Cir. 1993) (stating that the different concerns of debt and equity holders may call for distinct inquiry notice dates for the two classes of investors).

Finally, we question the District Court's conclusion that the New York Times article constituted a storm warning. The District Court reasoned that defendant Scolnick's statements in that article constituted "a significant departure from Merck's company line as to the explanation for the VIGOR study results." In re Merck, 483 F. Supp. 2d at 420. But Scolnick did not abandon the naproxen hypothesis; rather, he reiterated that Merck "found no evidence that Vioxx increased the risk of heart attacks" when it looked back at its data comparing Vioxx to other drugs and placebos and "that 'the likeliest interpretation of the data is that naproxen lowered . . . the thrombotic event rate' . . . ." App. at

654.[15] Even in the wake of the FDA warning letter, then, Merck continued to reassure the investing public that Merck stood behind the naproxen hypothesis, while acknowledging that another explanation (i.e., that Vioxx causes CV events) remained a possibility. See 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.") (citation and internal quotation marks omitted). It is also notable there was no "significant movement" of Merck's stock price following the article's publication. Newman, 335 F.3d at 195. Thus, we cannot conclude as a matter of law that this article constituted a storm warning.

In summary, we conclude that the District Court acted prematurely in finding as a matter of law that Appellants were on inquiry notice of the alleged fraud before October 9, 2001. As of that date, market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was plausible, at the very least. None suggested that Merck believed otherwise. Accordingly, in April 2002, the FDA approved a labeling change for Vioxx which stated that "[t]he significance of the cardiovascular findings [from the VIGOR study] is unknown." App. at 553. Merck continued to reassure the investing public at this time, explaining that the naproxen

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[15] The New York Times article also explained that "[t]he risk is hypothesized, not proved," and that "leading arthritis specialists . . . say that they are not concerned and that they prescribe the drugs for patients who may have heart disease." App. at 653.

hypothesis was "a position Merck has always had and now its [sic] quite clearly laid out in the labeling." App. at 559. On the record before us, there is no reason to suspect that Merck did not believe the naproxen hypothesis until the Harvard study in 2003 revealed an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo. This study for the first time belied Merck's repeated assurances that naproxen was responsible for the disparity in CV events in VIGOR and that Vioxx did not have a higher incidence of CVs compared to placebo or comparator NSAIDs, such as Celebrex.[16]

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[16] There are two statements in the dissent, although arguably going to minor issues, that call for a response. The dissent states that Scolnick's statement quoted in the October 9, 2001 New York Times article was "the first time [the statement that the VIGOR results could be explained by either the effect of naproxen or Vioxx] had been made by the company." Dissent Typescript op. at 46-47. In fact, as noted above, Alise Reicin, the Executive Director of Clinical Research at Merck Research Laboratories, had testified as to that possibility at the FDA's hearing before the AAC as early as February 8, 2000, more than eight months before the New York Times article. See supra p. 7.

Second, to the extent that the dissent suggests that the majority holds that fluctuations in stock price and analysts' ratings and projections are necessary to a finding of storm warnings, Dissent Typescript op. at 47, a rereading of the majority opinion will make clear that the majority agrees with the dissent that such factors are relevant to the storm warnings inquiry, but not required. See supra p. 28.

It is ironic that the dissent, although noting what might be viewed as Merck's misrepresentations, would apply the

V.

Conclusion[17]

For the reasons set forth, we will reverse the judgment of dismissal and remand to the District Court for further proceedings consistent with this opinion.

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statute of limitations to deprive plaintiffs of the opportunity to prove a viable case against Merck for such misrepresentations.

[17] Because we have concluded that the District Court erred in finding Appellants on inquiry notice of the alleged fraud at this stage of the litigation, we do not address Appellants' remaining arguments regarding the claims of plaintiffs who purchased stock after October 9, 2001 and the viability of Appellants' section 20A claims.

ROTH, Circuit Judge, dissenting.

I believe "storm warnings" alerting a reasonable investor of *possible* culpable activity on the part of Merck were evident more than two years prior to the filing of appellants' complaint. In particular, I believe that the FDA's September 17, 2001, warning letter, in and of itself, provided sufficient "storm warnings" to put the appellants on inquiry notice of their claims regardless of any significant change in stock price or analysts' stock ratings or projections at that time. I therefore respectfully dissent.

Under the "inquiry notice" test, the statute of limitations for securities claims "begins to run when the plaintiffs 'discovered or in the exercise of reasonable diligence should have discovered the basis for their claim' against the defendant." *Benak v. Alliance Capital Management L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (*quoting In re NAHC, Inc. Securities Litigation*, 306 F.3d 1314, 1325 (3d Cir. 2002) (citations omitted)). In order to establish that plaintiffs were on inquiry notice, a defendant must demonstrate that, as of a particular date, there existed "storm warnings" sufficient to alert "a reasonable investor of ordinary intelligence" to "*possible* wrongdoing" on the part of defendants. *Id.* (*quoting In re NAHC*, 306 F.3d at 1325) (explaining that the question is whether plaintiffs had "sufficient information of possible wrongdoing to place them on

'inquiry notice' or to excite 'storm warnings' of culpable activity") (emphasis added).

Furthermore, it is well established that "[t]he existence of storm warnings is a *totally objective* inquiry[,]" that is based on whether a "reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning[,]" *Mathews v. Kidder Peabody & Co., Inc.*, 260 F.3d 239, 252 (3d Cir. 2001) (emphasis added); *see also In re NAHC*, 306 F.3d at 1325. We do not require that plaintiffs "know all of the details or 'narrow aspects' of the alleged fraud to trigger the limitations period[,]" but rather "the period begins to run from the time at which plaintiff should have discovered the general fraudulent scheme." *In re NAHC*, 306 F.3d at 1326 (internal quotations and citations omitted). Most importantly, we recognize that triggering data for "storm warnings" may include any information that would alert a reasonable investor to the *possibility* that the defendants engaged in the "*general fraudulent scheme*" alleged in the complaint. *Id.* (emphasis added). Finally, such triggering data must "relate[] directly to the misrepresentations and omissions alleged." *DeBenedictis*, 492 F.3d at 217-18 (*quoting Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 171 (2d Cir. 2005)).

In applying the above inquiry notice standard to the instant case, I am reminded of a classic fairytale: *The Emperor's New Clothes*, by Danish author and

poet, Hans Christian Anderson.[18] As the child in *The Emperor's New Clothes* saw – that the Emperor walked naked down the street – any reasonable investor reading the FDA's September 17, 2001, warning letter could see the problem with Vioxx – the misrepresentation of its safety profile and the "possibility" that Merck had fraudulently misrepresented the cardiovascular safety of its "blockbuster" product. The warning letter to Merck, which was published on the FDA's public website, stated in pertinent part:

> *You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings* that were observed in the [VIGOR] study, and *thus, misrepresents the safety profile* for

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[18] In the story, two swindlers approached the Emperor, falsely claiming the ability to make beautiful clothes from cloth that could be seen only by those individuals fit for their positions or who were not imbecils. The Emperor immediately hired them. Word spread throughout the city about the unique quality of the cloth and the personal characteristics that an individual must possess to see clothes made of such material. After the swindlers finished weaving the Emperor's new clothes and presented them to him, neither the Emperor nor his most trusted servants would admit that they could not see the clothes for fear of appearing unfit or stupid. Instead, each exclaimed that the clothes were beautiful. Donning his new clothes, the Emperor walked in a procession through the city's streets. The townspeople also feared looking stupid in their neighbors' eyes. Like the Emperor and his servants, they proclaimed that the clothes were the most beautiful they had ever seen. It wasn't until a child exclaimed, "But, Daddy, he has nothing on!" that the crowd realized that the child spoke the truth.

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 [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*.

...

Your *minimizing* these potential risks and *misrepresenting* the safety profile for Vioxx *raise significant health and safety concerns*. 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*.

> ...
> We have idenitified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX," dated May 22, 2001, that is also *false or misleading* for similar reasons stated above. Additionally, *your claim in the press release that VIOXX has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading;* in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the naproxen treatment group (46 events, 1.1%) in the VIGOR Study.

App. at 713-14, 718 (emphasis added).[19]

The warning letter *clearly and explicitly* reprimanded Merck for its (1) deceptive and misleading conduct in publicly endorsing the

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[19] Also in the warning letter, the FDA identified specific statements made by Merck in promotional audio conferences and by Merck's sales force demonstrating Merck's minimization and misrepresentation of the increased heart attack rates of Vioxx-taking participants in the VIGOR study and several unsubstantiated superiority claims made by Merck about Vioxx. App. at 715-16, 718-19. Finally, the warning letter concluded with a corrective action plan which required Merck to issue a "'Dear Healthcare provider' letter to correct false or misleading impressions and information." App. at 719.

naproxen hypothesis as the sole explanation for the higher rate of cardiovascular events in VIGOR study participants taking Vioxx, *despite* knowing that any purported cardiovascular protective effect of naproxen was unproven, and (2) downplaying of potential safety problems in failing to disclose the possibility that Vioxx increases the risk of heart attack. As the letter explained, this was *not* the first time the FDA had charged Merck with misrepresenting Vioxx's safety profile. The language used in the letter was particularly strong and indicated the FDA's significant concern for the public's health. Also, the warning letter cannot be said to have constituted mere speculation, but was rather a formal report of "objective wrongdoing." *See Benak*, 435 F.3d at 402 (explaining that, in determining whether a plaintiff has inquiry notice, "[s]peculation should not be given the same weight as reports of objective wrongdoing"). Furthermore, the warning letter was published on the FDA's website where it would have been discovered by a reasonable Merck investor. *See In re NAHC*, 306 F.3d at 1325.

Moreover, the charges in the warning letter relate directly to the misrepresentations and omissions alleged in the appellants' complaint: that the company and certain of its officers and directors intentionally misrepresented the cardiovascular safety of Vioxx and, consequently, the impact that Vioxx would have on Merck's financial health. *See DeBenedictis*, 492 F.3d at 217-18; *see e.g.*, Amended Complaint, App. at 468 (stating that "Defendants made... materially false and misleading statements and omissions concerning... the safety profile of...

VIOXX"); App. at 470 (stating that "Defendants misrepresented the safety profile of VIOXX, including concealing and minimizing the significantly increased risk of heart attacks in patients taking the drug"); App. at 482 (describing a "wrongful scheme... which included the dissemination of materially false and misleading statements and concealment of material adverse facts"); App. at 497 (stating that "Defendants falsely conditioned the market to believe VIOXX was safe"). Accordingly, I believe that the FDA's warning letter to Merck sufficiently alerted a reasonable investor to the *possibility* that Merck fraudulently misrepresented the cardiovascular safety of Vioxx – its "blockbuster" product.[20]

Even assuming that the FDA's warning letter alone did not sufficiently excite "storm warnings,"

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[20] It is important to note that Merck's reliance on its naproxen hypothesis was proved to be unfounded from the beginning. Even before the FDA's warning letter was issued, an April 27, 2000, *Reuters* article reported that (1) a spokesperson for leading naproxen manufacturer, Roche Holding Ltd., explained that "[t]o [their] knowledge, naproxen does not prevent heart attack or stroke" and (2) an ABN Amro analyst indicated that "[m]edical authorities [he had] spoken to don't see any special reduction of such cardiovascular events in people taking naproxen." App. at 2288. Additionally, an August 21, 2001, *Bloomberg News Article*, reported a Merck representative's comment that "[Merck] already ha[s] additional data beyond what [the *JAMA* article] cite[s], and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." App. at 539. Even if this "additional data" included evidence that could support Merck's naproxen hypothesis, Merck never revealed the details of its purported "additional data."

the total mix of information in the public realm which followed the warning provided more than adequate "storm warnings" to put appellants on inquiry notice.

In response to the FDA's warning letter, there was widespread media and financial analyst coverage commenting on the FDA's charges against Merck, with some reports noting that such warnings are reserved for the more serious offenders. *See e.g.*, App. at 2353 (*Reuters*, September 24, 2001) (reporting that "U.S. Regulators have charged... Merck... with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks"); App. at 2752 (*Merrill Lynch*, September 24, 2001) (stating that "[t]he FDA issued a warning letter to Merck... [and] is looking for Merck to cease all violative promotional activities... . We do not see how this... can be helpful to Merck in promoting Vioxx"); App. at 2355 (*USA Today*, September 25, 2001) (reporting that "Merck's marketing efforts... have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter'... . So far this year, the FDA has sent drug companies fewer than a dozen warning letters, which the agency reserves for activities that raise significant public health concerns"); App. at 2768 (*UBS Warburg*, September 25, 2001) (stating that the "FDA [has] issue[d] [a] warning to Merck for marketing only one side of the Vioxx safety argument... . Merck was cited several times for promoting the story that the outcome of the VIGOR study was due to Naproxen being cardioprotective and that there is no unusual cardiovascular safety

risk with Vioxx."); App. at 2360 (*Associated Press*, September 25, 2001) (reporting that "Merck has argued that [the VIGOR study results make] Vioxx falsely look[] risky because naproxen thins the blood... and thus protect[s] against heart attacks... . 'In fact, the situation is not all that clear,' [according to] the FDA"); App. at 2757 (*Credit Suisse First Boston*, September 25, 2001) (stating that "the FDA [has] issued a warning letter citing Merck with making misleading statements in the promotion of... Vioxx"); App. at 2361 (*The Wall Street Journal*, September 25, 2001) (reporting that "Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks[,]" and "[w]hile the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year"); App. at 2363 (*The New York Times*, September 26, 2001) (stating that "[t]he [FDA] has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks"). Even appellants themselves recognized in their complaint that "FDA Warning Letters are sent only to address serious circumstances." App. at 1280.

Furthermore, in addition to the first lawsuit filed before the FDA's warning letter, three product liability and consumer fraud actions had been filed in September and October 2001, all alleging that Merck had misrepresented the cardiovascular safety of Vioxx. *See* App. at 1748 (May 29, 2001, product liability class action alleging that "Merck's own

research [demonstrated that] users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications..., [but that] Merck... [took] no affirmative steps to communicate this critical information to class members"); App. at 1557 (September 27, 2001, consumer fraud class action alleging that "Merck [had] omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including... cardiovascular problems... [and] purposely downplayed and/or understated the serious nature of the risks associated with Vioxx"); App. at 1574 (September 28, 2001, product liability and consumer fraud action alleging that Merck had "misrepresented that Vioxx was... safe and effective..., when in fact the drug causes serious medical problems such as an increased risk of cardiovascular events, including strokes, heart attacks and death"); App. at 1611 (October 1, 2001, product liability action alleging that Merck failed to "[]disclose[]" that "Vioxx causes heart attacks"). While these law suits did not allege *securities* fraud, the general allegations contained within these complaints relating to Merck's intentional misrepresentation with regard to Vioxx's safety similarly formed the basis of appellants' complaint.

Moreover, *The New York Times* article, dated October 9, 2001, quoted defendant Scolnick as explicitly stating that "[n]aproxen lowers the heart attack rate, *or Vioxx raises it*." App. at 2367 (emphasis added). Based on my review of the record, this express acknowledgment by a Merck representative of the possibility that Vioxx actually

raises the risk of heart attack appears to be not only the first time such statement had been made by the company, but also in stark contrast to Merck's prior representations. Therefore, because of what I perceive to be significant media and financial analyst attention directed at the explicit and serious nature of the FDA's warning letter, the allegations in the multiple lawsuits which followed, and Merck's change of tone in the October 9, 2001, article, I cannot see how a reasonable investor could not be aware of the *possibility* that Merck had been fraudulently misrepresenting the cardiovascular safety of Vioxx.

Because the objective evidence indicated the possibility of culpable activity on the part of Merck, a lack of significant stock movement and decreases in analysts' stock ratings and projections *do not negate* a finding of "storm warnings" under our inquiry notice standard. Appellants argue that "storm warnings" could not have existed prior to the 2003 Harvard Study because the total mix of public information did not have a negative effect on the price of Merck stock or cause analysts to drop their ratings for Merck or lower their projections for Vioxx sales. It is true, as the majority points out, that our past inquiry notice decisions have taken into consideration the market's response to disclosures alleged to constitute "storm warnings." However, I do *not* believe the law *requires* that, in order to make a determination that "storm warnings" in fact exist, the total mix of public information (purported to constitute "storm warnings") *must* have a negative effect on stock prices or cause analysts to drop their ratings or lower their projections. *See Benack*, 435

F.3d at 400 ("information [need only suggest] *possible* wrongdoing... to excite 'storm warnings'") (*quoting In re NAHC*, 306 F.3d at 1325) (emphasis added). As we recognized in *In re NAHC*:

> [S]torm warnings may take numerous forms, and we will not attempt to provide an exhaustive list. They may include, however, substantial conflicts between oral representations of the brokers and the text of the prospectus, ... the accumulation of information over a period of time that conflicts with representations that were made when the securities were originally purchased, *or any financial, legal or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.*

306 F.3d at 1326 n.5 (quoting *Mathews*, 260 F.3d at 252 (internal citations and quotations omitted)) (emphasis added). In my view, fluctuations in stock price and analysts' ratings and projections, although relevant, are *not* a *required* consideration in this circuit's objective "storm warnings" analysis. Here, the lack of a significant response from the market to the FDA's warning letter does not mean that the Emperor was not walking down the street with no clothes on. It merely means that the analysts saw the emperor's new clothes as Merck described them – not as reality presented.[21]

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[21] Regardless, Merck's stock price did decline sharply in the months leading up to October 9, 2001, as the public

Based on the foregoing, I submit there were sufficient "storm warnings" more than two years prior to the filing of appellants' complaint. At a minimum, I believe the FDA's September 17, 2001, warning letter constituted more than sufficient "storm warnings" to put appellants on inquiry notice of their claims, particularly since appellants fail to demonstrate either that they conducted a diligent investigation within two years of the accrual of such "storm warnings" or that they were unable to uncover pertinent information during that time period. Accordingly, because appellants waited over two years to bring suit, I conclude that their claims were filed out of time and were properly dismissed by the District Court.

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controversy about Vioxx raged. From January 1, 2001, to October 9, 2001, Merck's stock price declined by $24.32 or 27.4% App. at 1770-73. As appellants themselves alleged, "Merck's stock price began its slide in approximately *January of 2001, and continued and worsened after August of 2001* when the VIGOR cardiovascular data was presented more fully in the [JAMA article]." App. at 1225 (emphasis added).

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

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[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.

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 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 prothrombotic 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 antiinflammatory 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 nonprescription 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

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[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.

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 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 prothrombotic 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 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

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[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 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).

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").

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

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[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.

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

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 07-2431, 07-2432

IN RE: MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION
(MDL No. 1658)

CONSOLIDATED SECURITIES LITIGATION

Richard Reynolds, Steven LeVan, Jerome Haber and The Public Employees' Retirement System of Mississippi, the Court-Appointed Lead Plaintiffs and Plaintiffs Union Asset Management Holding AG, Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherrie B. Knuth, Joseph S. Fisher, M.D., Naomi Raphael, Rhoda Kanter, Park East, Inc. and Marc Nathanson, on behalf of themselves and the proposed class of purchasers of Merck securities during the period between May 21, 1999 and October 29, 2004,

Appellants

SUR PETITION FOR REHEARING

Present: SCIRICA, Chief Judge, SLOVITER, RENDELL, BARRY, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, and ROTH,* Circuit Judges

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* Hon. Jane R. Roth, Senior Circuit Judge, as to panel rehearing only.

The petition for rehearing filed by Appellees In Re: Merck & Co., Inc., in the above-entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied. Judge Roth would grant panel rehearing, Judge Rendell, Judge Ambro, Judge Fuentes, and Judge Jordan would grant rehearing en banc.

By the Court,

/s/ Dolores K. Sloviter
Circuit Judge

Dated: October 17, 2008
CMD/cc: All Counsel of Record