CHAPTER 14

MERCK & CO., INC., ET AL. v. RICHARD REYNOLDS ET AL.

ARTHUR MCMAHON, III AND NATHAN J. SCOTT

I. Why It Made the List

In *Merck v. Reynolds*, the United States Supreme Court is currently considering how to resolve a circuit split over when a plaintiff should be deemed to have constructive notice of possible securities fraud under section 10(b) of the Securities Exchange Act of 1934. The case may have great significance to public companies, because if it is decided adversely to Merck, it will be substantially harder for public companies to successfully assert a statute of limitations defense to securities fraud claims under section 10(b). Additionally, an adverse court decision on certain ancillary questions in the case may make pharmaceutical and life sciences companies that engage in a good faith public discourse about the safety and efficacy of their products more vulnerable to section 10(b) claims.

II. Facts of Case

Vioxx® is a non-steroidal anti-inflammatory drug (NSAID) developed by Merck & Co., Inc. (Merck). Traditional NSAIDs, such as ibuprofen and naproxen, have a mechanism of action that is associated with harmful gastrointestinal side effects. Vioxx, conversely, employed a different mechanism of action that did not cause the same gastrointestinal side effects as other NSAIDs, which gave Vioxx immense commercial potential.

Even before Vioxx was introduced to the market, some Merck employees were concerned that the drug could have harmful effects on the cardiovascular system, including increased risk of thrombotic events, such as myocardial infarction. Internal emails from as early as 1996 showed that Merck employees were aware of possible cardiovascular risks that could

threaten the drug's commercial viability.[1] A 1998 Merck internal study, the results of which were not made public for several years, suggested that Vioxx caused a greater number of cardiovascular events than a placebo or the other tested arthritis drug.[2] In November 1998, Merck submitted a New Drug Application to the Food and Drug Administration (FDA) for approval to market Vioxx. In May 1999, FDA approved Vioxx for the treatment of osteoarthritis, management of acute pain in adults and treatment of menstrual pain. Investors and market analysts viewed Vioxx as a potential commercial blockbuster.

In January 1999, Merck began the Vioxx Gastrointestinal Outcomes Research (VIGOR) study to examine Vioxx's gastrointestinal safety profile. The VIGOR study compared Vioxx to naproxen, the active ingredient in other pain relievers including Aleve® and Naprosyn®.[3]

The VIGOR study was completed in March 2000. In addition to showing that Vioxx produced fewer gastrointestinal side effects in comparison to naproxen, the study also showed significantly more cardiovascular events, such as heart attacks, in the group treated with Vioxx than in the group treated with naproxen.[4] Merck made the results of the VIGOR study public in a press release to investors on March 27, 2000. The press release stated that the incidence of serious gastrointestinal events among patients treated with Vioxx was significantly reduced compared to patients treated with naproxen. It also disclosed that the number of cardiovascular incidents experienced by patients treated with naproxen was significantly lower than in patients treated with Vioxx. The press release suggested that the difference in the number of cardiovascular events was attributable to naproxen's ability to block platelet aggregation, rather than to any tendency of Vioxx to increase the likelihood of cardiovascular events (the "naproxen hypothesis"). The press release 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. [5]

Merck cited no study or evidence that showed naproxen blocked platelet aggregation, instead presenting such information as accepted fact. The results of the VIGOR study were widely reported in medical journals and securities analyst reports, as well as in the press

---

1 *In re* Merck & Co., Inc. Securities, Derivative & "ERISA" Litigation, 543 F.3d 150, 154 (3d Cir. 2008).

2 *Id.*

3 *In re* Merck & Co., Inc., Securities, Derivative & "ERISA" Litigation, 483 F. Supp. 2d 407, 410 (D. New Jersey 2007).

4 *Id.* at 411.

5 Press Release, Merck & Co., Inc., Merck Informs Investigators of Preliminary Results of Gastrointestinal Outcomes Study with Vioxx (Mar. 27, 2000) (***available at*** http://dida.library.ucsf.edu/pdf/oxx15y10).

generally, initiating a public debate about whether the increase in cardiovascular events was caused by Vioxx or whether the naproxen hypothesis was the correct explanation for the increase.[6] Throughout this public debate, Merck consistently promoted the overall safety of Vioxx by attributing the VIGOR data on cardiovascular events solely to the cardioprotective effects of naproxen and denying that Vioxx had any pro-thrombotic effect. [7]

On September 17, 2001, FDA entered the public debate by issuing a Warning Letter to Merck taking issue with Merck's minimization of the cardiovascular findings of the VIGOR study by presenting the naproxen hypothesis in the promotional materials as if it were fact.[8] The letter stated, in relevant part:

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

The FDA Warning Letter called for Merck to cease promotional activities that minimized the seriousness of the cardiovascular risk associated with Vioxx and to issue a "Dear Healthcare Provider" letter to correct false or misleading information disseminated via the promotional campaign.[9] The letter was published on FDA's website on September 20, 2001. The price of Merck stock fell 6.6 percent between September 20, 2001, and September 25, 2001,

---

[6] ***In re*** Merck & Co., Inc., 483 F. Supp. 2d 407, 411.

[7] ***Id.*** at 412-13.

[8] Letter from Thomas Abrams, Director, Division of Drug Marketing, Advertising and Communications, Food and Drug Administration, to Raymond V. Gilmartin, President and CEO, Merck & Co., Inc., 1 (Sept. 17, 2001) (***available at*** http://www.fda.gov).

[9] FDA Warning Letter, at 7.

but rebounded by October 1, 2001, to a price slightly higher than its closing price before the letter was made public.[10]

Following the publication of the FDA Warning Letter, numerous articles on the safety profile of Vioxx were published in well-known media publications, including an article in the ***New York Times*** published on October 9, 2001, quoting Dr. Edward Scolnick, then president of Merck Research Laboratories, as stating the following regarding the results of the VIGOR study: "There are two possible interpretations … Naproxen lowers the heart attack rate, or Vioxx raises it." It went on to quote Dr. Scolnick as stating that the findings from studies to date were not sufficient to fully resolve the questions about the cardiovascular effect of Vioxx.[11] The article was not followed by significant movement in Merck's stock price.[12]

It was also in 2001 that the first Vioxx-related lawsuits were filed against Merck, although no securities claims were filed for another two years. A product liability class action was filed in the United States District Court for the Eastern District of New York in May 2001. Following publication of the FDA Warning Letter, a number of additional suits were filed, including a consumer fraud class action in New Jersey state court and a suit alleging consumer fraud claims in Utah state court.[13]

In October 2003, the results of a study by the Harvard-affiliated Brigham and Women's Hospital were released. According to an article in the ***Wall Street Journal*** reporting on the study, the study found an increased risk of heart attack in patients taking Vioxx compared with patients taking another arthritis pain reliever (Celebrex®) and a placebo. Merck's stock price fell below the Standard & Poor's 500 Index following the study and remained so for the rest of the relevant period.[14]

In September 2004, Merck was in the process of conducting another study on the long-term effects of treatment with Vioxx on colon polyps. An increased rate of cardiovascular events was observed and the study was stopped. On September 30, 2004, Merck announced a voluntary withdrawal of Vioxx from the market. The announcement was followed by a sharp drop in the price of Merck's stock.[15]

---

[10] ***In re*** Merck & Co., Inc., 543 F.3d 150 at 158.

[11] Gina Kolata, ***THE DOCTOR'S WORLD; For Pain Reliever, Questions of Risk Remain Unresolved***, N.Y. Times, Oct. 9, 2001, ***available at*** http://www.nytimes.com/2001/10/09/health/the-doctor-s-world-for-pain-reliever-questions-of-risk-remain-unresolved.html.

[12] ***In re*** Merck & Co., Inc., 543 F.3d 150 at 159.

[13] ***In re*** Merck & Co., Inc., 483 F. Supp. 2d 407, 415-16.

[14] ***In re*** Merck & Co., Inc., 543 F.3d 150 at 159.

[15] ***Id.*** at 159-60.

A. History of the Case

The first of 16 Vioxx-related securities fraud claims against Merck was filed on November 6, 2003, in the U.S. District Court for the Eastern District of Louisiana. That lawsuit was consolidated with the other securities fraud actions filed against Merck and several of its officers, directors and representatives into one securities class action in the U.S. District Court for the District of New Jersey.

The securities fraud class action against Merck consisted of allegations that Merck and the other defendants made misrepresentations and omissions that concealed information that suggested or demonstrated that Vioxx significantly increased the risk of cardiovascular events, and therefore that the prices paid by the plaintiffs for Merck securities purchased between May 21, 1999, and October 29, 2004, were artificially inflated, which, in turn, caused the plaintiffs to suffer losses when the price of Merck's stock declined following the withdrawal of Vioxx from the market.[16] The plaintiffs' complaint alleged that the defendants' misrepresentations and omissions violated section 10(b) of the Securities Exchange Act of 1934 (the Exchange Act), which is the subject of this discussion. The complaint also included allegations under section 20(a) and 20A of the Exchange Act and sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the Securities Act).

In order to maintain a private claim for securities fraud under section 10(b) of the Exchange Act, a plaintiff must demonstrate 1) a material misstatement or omission, 2) made with ***scienter*** (i.e., intentionally, knowingly or recklessly), 3) in connection with the purchase or sale of securities, 4) upon which the plaintiff relied and 5) that proximately caused the plaintiff's loss.

The defendants filed a motion to dismiss the action under Rule 12(b)(6) of the Federal Rules of Civil Procedure, on the grounds that the plaintiffs' claims were made after the expiration of the applicable statutes of limitation. Different statutes of limitations apply to the counts in the plaintiffs' complaint under the Exchange Act and the Securities Act. Section 804(a) of the Sarbanes-Oxley Act of 2002 (section 804(a)) applies to the Exchange Act claims, and provides that a complaint alleging "fraud, deceit, manipulation or contrivance" under the Exchange Act may be brought no later than the earlier of two years after the "discovery of the facts constituting the violation," or five years after the violation.[17] Claims under the Securities Act must be made 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."[18]

---

[16] ***In re*** Merck & Co. Inc., 483 F. Supp. 2d 407 at 410.

[17] 28 U.S.C. § 1658(b).

[18] 15 U.S.C. § 77m.

B. Circuit Split: Constructive Discovery and Inquiry Notice

Although the statute itself refers only to "discovery," most federal courts that have interpreted the statute of limitations found in section 804(a), including the Third Circuit, have recognized that the statute of limitations period may be triggered either by actual discovery of the facts constituting the violation or by constructive discovery of those facts. For purposes of the statute of limitations analysis, plaintiffs are deemed to have knowledge of all information that they could have discovered through diligent research up to the date of determination.[19]

Whether there has been constructive discovery of the facts constituting a violation depends on whether a defendant can establish a point at which the plaintiff was on "inquiry notice" of the alleged fraud. As the concept is applied in most federal circuits, a plaintiff is on inquiry notice when the plaintiff discovered, or in the exercise of reasonable diligence should have discovered, sufficient evidence of wrongdoing or "storm warnings" of culpable activity such that a reasonable investor would have investigated further.[20] Storm warnings may include any financial, legal or other data that would alert a reasonable person to the probability that material misstatements or omissions had been made. Once a storm warning occurs, the plaintiff has a duty to investigate to see if it has a basis for a claim.

Although the circuits are in broad agreement on the general notion of inquiry notice, *Merck v. Reynolds* comes at a time when there is a great division and substantial confusion both between and within the circuits as to what sort of information constitutes a storm warning sufficient to put a plaintiff on inquiry notice and on precisely when the statute of limitations begins to run after inquiry notice has been established. At the center of the first split between the circuits is the question of whether a plaintiff must possess (or be deemed to possess) information bearing on all of the elements of a section 10(b) violation in order to be on inquiry notice of such a potential violation. In particular, the circuits differ on whether and to what extent a storm warning must include some indication of ***scienter***, i.e., some indication that the misstatement giving rise to the alleged section 10(b) violation was intentional, reckless or knowing. Until 2008, the circuits appeared to agree that discrete, specific evidence of ***scienter*** was not necessary. In taking this approach, the courts recognized that a warning of a relevant material misstatement ought, in most cases, carry with it a warning of ***scienter***: A prudent, diligent investor who discovers evidence of a material misstatement cannot reasonably fail to consider and investigate the possibility that such a misstatement was not innocent. Unsurprisingly, the Ninth Circuit was the first to deviate from this standard in a case that the dissenting judges recognized put the court "in left field again." In *Betz v. Trainer Wortham & Company, Inc.*,[21] the court held that a plaintiff would be on inquiry

---

[19] *In re* Merck & Co., Inc., 483 F. Supp. 2d at 418.

[20] *Id.*

[21] 519 F.3d 863 (9th Cir. 2008).

notice of a section 10(b) violation only when the plaintiff had, actually or constructively, discovered specific facts indicating that the defendant had acted with ***scienter***. The court did not find that the plaintiff had been put on inquiry notice in that case because there was no evidence that the plaintiff was "intentionally or deliberately and recklessly misled."[22] Although earlier Third Circuit cases followed the majority on the ***scienter*** question (***see,*** e.g., ***Mathews v. Kidder Peabody***) as discussed below, in ***Merck*** a divided Third Circuit joined its California colleagues in holding that discovery of ***scienter*** was an essential part of inquiry notice. In ***Merck***, the court analyzed the many apparent storm warnings identified by the District Court, holding that they were not storm warnings for purposes of a securities fraud claim because the voluminous evidence cited did not give the plaintiffs "reason to suspect that Merck did not believe the naproxen hypothesis"[23]—even though the evidence discussed in the case included evidence that there were no data to support the hypothesis, and that many experts and analysts did not believe it.

The circuits are likewise divided on the question of when the statute of limitations begins to run once the plaintiff has been put on inquiry notice. A number of circuits have ruled that the statute of limitations begins to run immediately once the plaintiff has been put on inquiry notice.[24] Basing their decisions on the premise that the very purpose of the statute of limitations period is to give the plaintiff time to conduct its inquiry and build its case, these circuits do not delay the start of the period to provide additional time for such an inquiry. Other circuits, conversely, follow a two-step approach that gives plaintiffs an additional period for inquiry before the statute of limitation begins to run. This window is not based upon the actual timing or facts of the plaintiff's investigation (if any). Rather, in determining how long to delay the start of the statute of limitations period, these courts consider how long it would take a hypothetical reasonably diligent plaintiff to conduct such an investigation. The Second Circuit has taken a similar approach, providing for the statute of limitations period to be delayed for a hypothetically reasonable investigation period. However, the Second Circuit gives a plaintiff the benefit of this delay only if it has actually conducted an investigation.

C. The District Court Decision

The District Court, in considering the defendant's motion to dismiss the securities fraud claims on statute of limitations grounds, analyzed the plentiful information available in the public realm from 1999 through 2004, including press releases and investor communications by Merck, articles in newspapers and periodicals, both medical and general

---

[22] *Betz* at 878.

[23] *In re* Merck & Co., Inc., 543 F.3d at 172.

[24] *See,* e.g., Franze v. Equitable Assurance, 296 F.3d 1250 (11th Cir. 2009) and GO Computer, Inc. v Microsoft Corp., 508 F.3d 170 (4th Cir. 2007).

circulation, and specific communications from regulators such as FDA to determine whether there were sufficient storm warnings to establish inquiry notice prior to November 6, 2001.

Citing *Mathews v. Kidder, Peabody & Co., Inc.*,[25] the District Court stated that "[I]f storm warning existed, and the plaintiffs choose not to investigate, we will deem them on inquiry notice of their claims." The District Court summarized its conception of inquiry notice for the claims as follows:

> [I]nquiry notice exists when the plaintiffs discovered, or in the exercise of reasonable diligence should have discovered the general fraudulent scheme. It is at that point that the clock starts to run on the limitations period.[26]

Under this loose standard, discrete, specific indications of the defendant's *scienter* were not necessary for the plaintiff to be placed on inquiry notice. Applying this standard, the District Court found that the plaintiffs were on inquiry notice no later than October 1, 2001, the date that the *New York Times* published the article quoting Dr. Scolnick's statements acknowledging that the naproxen hypothesis was unproven. The District Court considered the many news articles as well as the FDA Warning Letter and statements by Merck in finding that there were sufficient storm warnings to put the plaintiffs on notice that Merck's public disclosures about the safety of Vioxx might be materially inaccurate. The court stated that "an overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX had accumulated in the public realm."[27] Because the inquiry notice date found by the District Court was more than two years prior to the filing of the first securities fraud claims against Merck on November 6, 2003, the District Court held that the applicable statutes of limitations had run before the plaintiffs filed their securities fraud claims and granted the defendants' motion to dismiss.[28]

As discussed below, the District Court and the Court of Appeals had materially different views of precisely which Merck misstatement gave rise to the plaintiffs' claims. Unlike the Circuit Court, which appears to have concluded that Merck never actually believed the naproxen hypothesis was plausible and consequently misstated its opinion and belief when it publicly advocated the hypothesis, the District Court took the simpler approach of considering the substantive accuracy of Merck's statements about Vioxx itself. In the District Court's view, to the extent Merck made a misstatement, it simply misstated how safe Vioxx was.

---

[25] 260 F.3d 239 at 256 (3d. Cir. 2001).
[26] *In re* Merck & Co., Inc., 483 F. Supp. 2d at 418.
[27] *Id.* at 419.
[28] *Id.* at 423-25.

III. Court Ruling

The plaintiffs challenged the dismissal of the case by the District Court in the Third Circuit Court of Appeals, and the Court of Appeals reversed the District Court's decision. The Court of Appeals disagreed with the District Court's finding that the information identified by the District Court, including the articles published in national newspapers and medical journals, the FDA Warning Letter and the Vioxx-related lawsuits filed against Merck, constituted storm warnings for purposes of the plaintiffs' section 10(b) fraud claim.

IV. Rationale for Decision

As discussed above, an essential element of a section 10(b) claim is that the misstatement or omission be made with ***scienter***. Under the Court of Appeals' reasoning, storm warnings sufficient to establish inquiry notice for a securities fraud claim would have to indicate to a plaintiff not only that a misrepresentation was made, but that the person making the misrepresentation knew that the statement was false or materially misleading when made.[29]

In examining the District Court's analysis of the information available on Vioxx prior to November 2001, the Circuit Court held that the various storm warnings identified by the District Court were not, in fact, storm warnings for purposes of a securities fraud claim, because they did not provide any evidence of ***scienter*** on the part of the defendants. The Circuit Court stated that the FDA Warning Letter was not a storm warning because the FDA Warning Letter "did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of the hypothesis."[30] Likewise, the Circuit Court disagreed with the characterization of the non-securities fraud lawsuits filed against Merck in 2001 as storm warnings because none of those suits were allegations of securities fraud, even though several included allegations of common law fraud.

In addition to the question of whether storm warnings must indicate ***scienter*** in order to establish inquiry notice in the case of a section 10(b) claim, the Circuit Court also considered the movement of Merck's stock price in the market in reaction to the various statements described by the District Court as storm warnings. The Circuit Court held that the reaction of the market to the various reports, articles and other information identified as storm warnings by the District Court was also relevant in determining whether those events were storm warnings for purposes of a section 10(b) claim. The Circuit Court found that although the market price of Merck's stock following publication of the FDA Warning Letter dipped slightly, the fact that it did not show "significant movement" supported the conclusion that the letter "did not constitute a sufficient suggestion of securities fraud to trigger a storm

[29] ***In re*** Merck & Co., Inc., 543 F.3d at 167.
[30] ***Id.*** at 170.

warning of culpable activity under the securities laws."[31] It also considered the fact that several securities analysts did not change their ratings for Merck stock and their projections for Vioxx revenues after the Warning Letter was published.[32]

Significantly, the Circuit Court's view of the specific misstatement underlying the plaintiffs' section 10(b) claim differed from that of the District Court. The District Court, understandably, had identified Merck's misstatements as simply being its public statements that downplayed or denied the cardiovascular risks of Vioxx. In other words, in the District Court's view, Merck's misstatement was that Vioxx carried with it less cardiovascular risk than ultimately proved true. The Circuit Court, in contrast, took the more, and perhaps artificially, nuanced position that Merck's actionable misstatement related to its subjective belief in the tenability of the naproxen hypothesis. In other words, Merck's misstatement was that it purported to believe the naproxen hypothesis when it in fact did not.

The Circuit Court summed up its assessment of the District Court's conclusion that there were storm warnings sufficient to put the plaintiffs on inquiry notice of the securities fraud claims by stating:

> [W]e conclude that the District Court acted prematurely in finding as a matter of law that Appellants [plaintiffs] 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.[33]

Judge Roth of the Court of Appeals dissented, agreeing with the District Court that the various storm warnings it identified would have put a reasonable investor on inquiry notice of the section 10(b) claim. She pointed out that the Third Circuit's previously established inquiry notice standard does not require that a plaintiff "know all of the details or 'narrow aspects' of the alleged fraud," but rather the "general fraudulent scheme."[34] Accordingly, there was no need to find storm warnings that showed a belief that the naproxen hypothesis was false, rather than simply unproven, on the part of the defendants in order to find storm warnings. She argued that the FDA Warning Letter alone was a storm warning sufficient to establish inquiry notice because it

> …***clearly and specifically*** reprimanded Merck for its (1) deceptive and misleading conduct in publicly endorsing the naproxen hypothesis as the sole explanation for the higher rate of cardiovascular events in the VIGOR study

---

[31] ***In re*** Merck & Co., Inc., 543 F.3d at 171.
[32] ***Id.***
[33] ***Id.*** at 172.
[34] ***Id.*** at 173.

> participants taking Vioxx, ***despite*** knowing that any purported cardiovascular protecting 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.[35]

V. Impact of Decision

The Supreme Court granted certiorari to review the Third Circuit's decision on May 26, 2009, and heard oral arguments on November 30, 2009.

A. Merck's Brief

Merck articulated the specific question before the Court as follows:

> Whether the court of appeals erred by holding that, for purposes of determining when the limitations period begins to run, a plaintiff is not on inquiry notice of the securities fraud claim until the plaintiff possesses information, obtained without the benefit of any investigation, that the defendant acted with scienter.

Needless to say, Merck took the position that the Circuit Court did err, and that a storm warning need not include discrete or explicit information indicating the defendant's ***scienter***. In identifying this error, the petitioner/defendant called attention to the distinction between a statute of limitations defense and a pleadings defense and argued that the Circuit Court's approach blurred the two defenses in a manner that vitiated the statute of limitations defense and rendered the concept of inquiry notice effectively useless.

On the first point, Merck argued that following the Third Circuit's approach would effectively eliminate the distinction between a pleadings defense and a statute of limitations defense, which would be impracticable for courts and prejudicial to defendants. As Merck put it, the Third Circuit's rule "would effectively require a court to engage in the difficult task of passing on the sufficiency of the allegations in a complaint before determining whether the complaint was untimely."[36] Likewise, being required to assert both defenses at the same time would put the defendant in the untenable position of, on the one hand, having to argue that the plaintiff was aware of information indicating all elements of the violation more than two years before it filed its complaint but, on the other hand, having to argue that the complaint the plaintiff actually filed failed to assert all of the elements of the violation. Surely,

---

[35] *Id.* at 174.

[36] Petr.'s Br. 30.

Merck argued, effectively eliminating the statute of limitations defense from section 10(b) cases cannot be the right result.

On the second point, Merck argued that the Third Circuit's approach, under which a plaintiff would only be on inquiry notice when it possessed "information specifically relating to all of the elements of the violation, including scienter"[37] defeated the purpose of inquiry notice because it left plaintiff little to inquire about. Citing the dissent in the Ninth Circuit's *Betz* case, Merck pointed out that a storm warning "does no work" if it is not effective until the "hurricane makes landfall."[38]

Merck also argued that requiring a storm warning to include discrete indications of ***scienter*** is incompatible with the concept of inquiry notice and impractical as an evidentiary matter. In the first place, in Merck's view a warning of a material misstatement under most circumstances necessarily carries with it a warning of ***scienter***. In other words, when a plaintiff becomes aware that the defendant has made a material misstatement or an omission, a reasonable plaintiff "should at least ***suspect the possibility*** that the defendant did so with ***scienter***."[39] Secondly, Merck pointed out that discrete evidence of ***scienter*** is neither necessary nor common in successful section 10(b) claims. Rather, ***scienter*** "is usually proved through inferences from circumstantial evidence."[40] Indeed, it would be a perverse result for the court to hold that discrete, specific evidence of ***scienter*** is necessary for the defendant to succeed with a statute of limitations defense when such evidence is not necessary for the plaintiff to prevail on the merits.

B. The Plaintiffs' Brief

Unsurprisingly, the plaintiff/respondents' brief largely followed the reasoning of the Circuit Court's opinion. Although one of the questions it presented was generally similar to Merck's question as to the necessity of evidence of ***scienter*** to a storm warning, it also included a question that emphasized the Third Circuit's view that the relevant misstatements were Merck's statements regarding its belief in the plausibility of the naproxen hypothesis rather than its statements as to the overall cardiovascular safety of Vioxx. Specifically, plaintiffs' questions were:

> 1. Whether a reasonable Merck investor could have discovered petitioner's statements were material misrepresentations of belief and opinion as charged in respondent's complaint earlier than November 6, 2001.
> 2. Whether scienter is among the facts constituting [a] violation within the

[37] Petr.'s Br. 23.
[38] *Id.*
[39] *Id.* at 22.
[40] *Id.*

> meaning of Section 1658(b)(1) and, if so, whether a reasonable Merck investor should have discovered petitioner's fraudulent intent earlier than November 6, 2001.

The plaintiffs' argument was premised on the notion that determining whether a plaintiff is on inquiry notice of a possible section 10(b) violation is not dispositive to the constructive discovery analysis, but instead is merely a subsidiary step to determining whether the statute of limitations should begin to run at a particular time in a particular case. Under this approach, the statute of limitations period would not begin to run simply because "an investor had information to put him on his guard."[41] Instead, plaintiffs urged the Court to adapt, in essence, the two-step, hypothetically reasonable investor approach found in other circuits. Plaintiffs took care to emphasize, however, that this analysis must consider what information actually would have been available to a hypothetical inquiring plaintiff, and that the plaintiff should not be deemed to have information for which it lacked the "means of discovery."[42] Consistent with the bias of professional securities plaintiffs, plaintiffs cautioned the court that plaintiff should not be charged with knowledge "exclusively within a defendant's control,"[43] because, presumably, a public company defendant will necessarily go to any length to conceal it. To do otherwise, they argued, would benefit "those defendants who are best at hiding their fraud."[44] Plaintiffs followed the Third Circuit's argument on the need for storm warning to include discrete evidence of ***scienter*** as well. Interestingly, though, the plaintiffs dismissed Merck's concern that even a well-pled section 10(b) case might not include discrete, direct, evidence of ***scienter*** by arguing that "circumstantial facts can provide investors with a sufficient basis to conclude that a defendant's misconduct was committed with scienter."[45] If facts giving rise to a mere underlying inference of ***scienter*** are sufficient for a storm warning, it is, in certain respects, difficult to see how the plaintiffs' position differs from Merck's.

C. Oral Argument

While it is usually difficult and always dangerous to try to divine how the Court will decide from what is discussed in oral argument, reviewing the Justices' questions and comments can, at least, provide some insight into how the individual Justices conceive the questions before the Court and what information they believe is necessary to answer them. In ***Merck v. Reynolds***, the general tenor of the Justices' questioning suggested that Justices throughout the ideological spectrum were sympathetic to the argument that a storm warning should include at least some indication of ***scienter***. The Justices were less consistent on the question

---

[41] Respt.'s Br. 17.
[42] Respt.'s Br. 32
[43] *Id.*
[44] *Id.* at 17.
[45] *Id.* at 19.

of precisely when the statute of limitations period ought to begin to run after the plaintiff is put on inquiry notice.

Interestingly, the Justices devoted a substantial amount of time to discussion of the history of and justification for the broader concept of applying constructive discovery in section 10(b) statute of limitations cases, presumably because section 804(a) itself, unlike the statutes of limitations for similar causes of action under the Securities Act, does not expressly contemplate constructive discovery. It seems unlikely that the Court would reject a concept that has broad approval in both the circuit courts and Congress. On the other hand, the fact that the Justices felt the need to spend time establishing that any type of constructive discovery is appropriate under section 804(a) may suggest that the Court will take a fairly narrow, plaintiff-friendly approach to its application.

On the question of ***scienter***, Justice Scalia was unconvinced by Merck's argument that evidence of a material misstatement ought to carry with it an inference of ***scienter***, pointing out that a defendant "can misrepresent something without having ***scienter*** to defraud."[46] Justice Ginsburg's rationale for requiring a storm warning to include discrete evidence of ***scienter*** was based on the premise that a storm warning ought to include all the elements of a well-pled claim: "Why not say because ***scienter*** is an element of the claim, and you can't get your foot in the door in the court unless you can plead that with particularity, that it's only when you have that indication that you have what you call inquiry notice?"[47] Justice Kennedy simply made the conclusory observation that "[y]ou have to have specific evidence of ***scienter***."[48]

The Justices were more divided on the question of the effect of inquiry notice. Justice Ginsburg seemed to endorse the two-step approach when she asked Merck's counsel "How would the most diligent plaintiff have gone about finding out whether Merck really had no good faith belief in this so-called naproxen hypothesis?"[49] Similarly, Justice Breyer seemed sympathetic to both the ***scienter*** requirement and the two-step approach as he described a hypothetical situation where the only person with evidence of the defendant's ***scienter*** was being held in jail incommunicado for three years. Under the pure inquiry notice approach, Justice Breyer complained, the plaintiff is "going to have to file his complaint before he could have the evidence that there was scienter. Now, that doesn't make sense to me."[50] Justice Alito and Chief Justice Roberts, on the other hand, shared Merck's concern that the two-step approach makes the statute of limitations period unnecessary and the concept of inquiry notice valueless. Questioning plaintiff's counsel, Justice Alito asked "why, then, did Congress allow [two] years after that? At that point, the plaintiff has everything that's necessary

---

[46] Transcript at 9.
[47] *Id.* at 18.
[48] *Id* at 12.
[49] *Id* at 7.
[50] *Id* at 19.

to file a complaint. So why does the plaintiff need [two] years after that point?"[51] As Chief Justice Roberts put it, under the plaintiff's approach "inquiry notice has nothing to do with anything."[52] Justice Alito echoed this view, chiding plaintiff's counsel "under your position … the concept of inquiry notice becomes essentially very unimportant, if not completely meaningless."[53]

On other topics, Justice Ginsburg seemed to share the Third Circuit's view that the market's muted response to the FDA letter strongly suggested that the letter was not an effective storm warning, observing to Merck's counsel that "the market apparently accepted this … there were not signals from the market itself."[54] Justice Kennedy, on the other hand, expressed skepticism about the merits of the plaintiffs' case: "Well, it does seem to me that even if we adopt your theory of the case, there is some problem with the allegation that there was fraud, because Vioxx did not—because Merck did not disclose that the hypothesis was only hypothetical, and the FDA August letter made that clear. So it seems to me you may have a problem as to that aspect of the case."[55]

D. Implications to Pharmaceutical and Life Sciences Companies

Merck v. Reynolds has a number of potentially significant implications, both for public companies generally and for companies in the pharmaceutical and life sciences industries. Most simply, if the Supreme Court creates a national rule that is similar to the approach the Third Circuit took in *Merck*, public companies will be substantially less likely to succeed with statute of limitations defenses in section 10(b) cases. Because *scienter* is frequently proved by inference and circumstantial evidence in section 10(b) cases, requiring storm warnings to include all the elements of a section 10(b) claim is likely to make it very hard for defendants to establish that a plaintiff has been put on inquiry notice. Similarly, the Third Circuit's two-step, "hypothetical plaintiff" approach to constructive discovery analysis is very difficult for a court to administer and will necessarily result in the statute of limitations period for most cases being extended substantially beyond what it would be under a pure inquiry notice approach. Because statute of limitations defenses, especially when asserted in a motion to dismiss, have traditionally been a relatively quick and inexpensive way for public companies to protect themselves from nuisance Exchange Act suits, it would be particularly unfortunate for public companies if the Court decides *Merck* in a way that impedes companies' ability to employ this defense.

---

[51] *Id* at 37.
[52] *Id* at 48-49.
[53] *Id* at 46.
[54] *Id* at 14.
[55] *Id* at 42.

The nature of the drug and device development and approval process, and the frequent and detailed public disclosure that public pharmaceutical and life sciences companies make regarding the progress of important products, makes these companies particularly attractive targets of section 10(b) suits. Indeed, in recent years, pharmaceutical and life sciences companies have been the subjects of a vastly disproportionate number of section 10(b) suits. Moreover, given that these companies have had a similarly disproportionate amount of success in defending themselves from such suits, it would appear that pharmaceutical and life sciences companies tend to receive a large number of relatively weak, opportunistic claims—precisely the sorts of claims against which the statute of limitations defense is an efficient and effective remedy and a more palatable approach than settling for nuisance value. Consequently, all public companies will be affected adversely if the Supreme Court decides ***Merck*** in manner that vitiates the statute of limitations defense, but pharmaceutical and life sciences companies are likely to be particularly hurt.

Although there is no related question directly before the Court, the Third Circuit's view (which appears to have been adopted after the fact by the plaintiffs) that, in essence, Merck's advocacy of the naproxen hypothesis could in itself be an actionable misstatement under section 10(b) ought to be particularly troubling to pharmaceutical and life sciences companies because it has the potential to make them more vulnerable to section 10(b) claims when they merely engage in a public discussion with regulators about the safety and efficacy of their products. While the federal courts have recognized that a securities issuer that makes an intentional misstatement about what it believes may be subject to liability under section 10(b), characterizing Merck's proposal of a plausible alternative hypothesis explaining the results of the VIGOR study as an intentional and actionable misstatement of belief would extend the reach of private 10(b) claims into dangerous and inappropriate territory and is likely to discourage manufacturers from engaging in good faith advocacy in support of potentially valuable products. Moreover, asking the courts to engage in a hindsight evaluation of a manufacturer's subjective state of mind about a product in development seems unfair, impracticable and gravely vulnerable to mistake. In light of both the likely increase in opportunities for section 10(b) claims it will bring and the practical difficulties in adjudicating such suits, we fear that a final decision in ***Merck*** that endores the Third Circuit's "misstatement of belief" theory is very likely to encourage an already brazen plaintiffs' bar to bring still more weak, opportunistic suits against pharamceutical and life science companies and to increase the settlement cost of those suits.

VI. Conclusion

Lest anyone think that we have overstated either the flimsiness of the typical life sciences private section 10(b) action or the mischief it can cause, in the second quarter of 2009, at the very time Merck's appeal of the private section 10(b) action was before the Court, the Division of the Enforcement of the Securities and Exchange Commission terminated its investigation of the Vioxx matter without sanctioning or charging Merck or any of its personnel in any way.[56] In other words, Merck has been required to go to the effort and expense of adjudicating a private 10(b) claim before the District Court, the Circuit Court and the Supreme Court, when the national agency that specializes in investigating and prosecuting securities law violations has concluded that the very same facts do not support a public 10(b) action, or even a lesser sanction.

[56] *See, e.g.*, Peter Loftus, ***Merck Sees $80 Million Vioxx Settlement***, Wall St. J., Aug. 3, 2009.