No. 08-905

IN THE
# Supreme Court of the United States

MERCK & CO., INC., ET AL.,
*Petitioners,*

v.

RICHARD REYNOLDS, ET AL.,
*Respondents.*

**On Writ of Certiorari to the United States Court of Appeals for the Third Circuit**

## BRIEF FOR RESPONDENTS


MAX W. BERGER
WILLIAM C. FREDERICKS
ELLIOTT J. WEISS
BRUCE D. BERNSTEIN
ANN M. LIPTON
BOAZ A. WEINSTEIN
ADAM H. WIERZBOWSKI
BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 554-1400

DAVID C. FREDERICK
*Counsel of Record*
GREGORY G. RAPAWY
MICHAEL E. JOFFRE
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900


October 19, 2009

*(Additional Counsel Listed On Inside Cover)*

DAVID A.P. BROWER
JESSICA J. SLEATER
BROWER PIVEN
A Professional Corporation
488 Madison Avenue
New York, New York 10022
(212) 501-9000

MATTHEW GLUCK
RICHARD H. WEISS
MATTHEW A. KUPILLAS
ROLAND W. RIGGS
MILBERG LLP
One Pennsylvania Plaza
New York, New York 10119
(212) 594-5300

JULES BRODY
MARK LEVINE
STULL, STULL & BRODY
6 East 45th Street, 5th Floor
New York, New York 10017
(212) 687-7230

## QUESTIONS PRESENTED

Under 28 U.S.C. §1658(b)(1), a limitations period of two years for a private securities-fraud action commences with "the discovery of the facts constituting the violation." The questions presented are:

1. Whether a reasonable Merck investor should have discovered petitioners' statements were material misrepresentations of belief and opinion as charged in respondents' complaint earlier than November 6, 2001.

2. Whether scienter is among the "facts constituting [a] violation" within the meaning of §1658(b)(1); and, if so, whether a reasonable Merck investor should have discovered petitioners' fraudulent intent earlier than November 6, 2001.

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## INTRODUCTION

In the late 1990s, Merck perceived an anticipated new "blockbuster" drug, Vioxx, to be critical to its future financial prospects. The company's non-public internal data, however, indicated that Vioxx might cause serious cardiovascular risks. Recognizing Vioxx's importance, Merck executives embarked on a scheme to obscure those likely risks.

In 1999, after Merck's rival Pfizer had started a large clinical trial involving the competing drug Celebrex, Merck began a similar large-scale study, Vioxx Gastrointestinal Outcome Research ("VIGOR"). VIGOR's results indicated that Vioxx users had a significantly higher incidence of adverse cardiovascular events than users of naproxen. Because those results threatened Vioxx's commercial viability, Merck concocted a theory to explain them: VIGOR's results stemmed from cardio-*protective* qualities of naproxen, rather than any cardio-*damaging* attributes of Vioxx. Merck's theory, which it consistently promoted to the financial and medical communities, became known as the "naproxen hypothesis."

Merck's gambit succeeded. Based on Merck's public assurances that data from its other, non-public clinical trials "showed no indication" (JA293) that Vioxx users experienced more adverse cardiovascular events than patients taking placebo or comparator drugs other than naproxen, the financial and medical communities generally accepted the naproxen hypothesis as the most likely explanation of VIGOR's results. Although the market knew the hypothesis was unproven, no one questioned the sincerity of Merck's belief in it or whether Merck had a reasonable basis to advance it. Vioxx sales continued to grow, totaling more than $8 billion during 2001-

2004, and Merck's stock price remained artificially high.

On September 30, 2004, Merck suddenly and unexpectedly withdrew Vioxx from the market. In response, Merck's stock price dropped precipitously. Four weeks later, *The Wall Street Journal* ("*WSJ*") published leaked internal Merck emails written years before revealing Merck's longstanding belief that Vioxx caused adverse cardiovascular events.

Respondents allege that petitioners[1] repeatedly and falsely stated that Merck believed in the naproxen hypothesis and that those false representations of belief caused the market to conclude that Merck's revenue stream from Vioxx would remain secure. After convincing *doctors* to write billions of dollars of prescriptions up until Vioxx was suddenly withdrawn from the market in 2004, Merck now argues that its own *investors* were on notice of its fraud before November 2001. To support its counter-intuitive theory, Merck asks the Court to interpret the two-year discovery prong of 28 U.S.C. §1658 as running from the first information "sufficiently suggestive of wrongdoing." Br. 20. Merck claims that it is legally irrelevant what kind of wrongdoing is suggested or whether the available information could lead to facts showing a violation of §10(b) of the Securities Exchange Act of 1934.

Merck's position cannot be reconciled with §1658's express command that the two-year limitations period does not begin to run until there has been "discovery of the facts constituting the violation" of §10(b). This Court should reject Merck's unsupportable reading of §1658 as inconsistent with text,

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[1] Petitioners hereafter are referred to collectively as "Merck."

precedent, and the purposes of the federal securities laws. The Court can also readily affirm the Third Circuit on the narrow ground on which it decided this case: two years before filing this action, respondents had no basis for even suspecting that Merck had materially misrepresented its opinion.

## STATEMENT

### A. Statutory And Doctrinal Background

In response to reports of widespread abuses in the securities industry, Congress enacted the Securities Act of 1933 ("1933 Act") and the Securities Exchange Act of 1934 ("1934 Act"). To advance their objective of "honest markets," *Basic Inc. v. Levinson*, 485 U.S. 224, 230 (1988) (internal quotations omitted), 1934 Act §10(b) forbids the use of "any manipulative or deceptive device or contrivance" "in connection with the purchase or sale of a security." 15 U.S.C. §78j(b).

In *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), this Court drew from the "contemporaneously enacted express remedial provisions" of the 1933 and 1934 Acts to impose a statute of limitations for the implied right of action it had earlier recognized under §10(b). Finding the language of 1934 Act §9 (prohibiting manipulation of security prices) most appropriate, *Lampf* held that "[l]itigation instituted pursuant to §10(b) and [Securities and Exchange Commission ("SEC")] Rule 10b-5 . . . must be commenced within one year after the discovery of the facts constituting the violation and within three years after such violation." *Id.* at 364.

In 2002, in response to corporate frauds including Enron and Worldcom, Congress amended 28 U.S.C. §1658(b) to extend the limitations period for §10(b) claims, but preserved the language from §9. As a Senate sponsor stated: "[W]e are not suggesting

changing the basic standards of the law on a statute of limitation. . . . We are perfectly willing to have exactly the same words as the law says now, with the exception the statute is slightly longer." 148 Cong. Rec. 12,502 (2002) (statement of Sen. Leahy). In relevant part, §1658(b) provides:

> [A] private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws, as defined in section 3(a)(47) of the [1934 Act] (15 U.S.C. 78c(a)(47)), may be brought not later than the earlier of –
>
> (1) 2 years after the discovery of the facts constituting the violation; or
>
> (2) 5 years after such violation.

## B. Nature Of The Action

### *1. Information that was publicly available*

Merck is a multibillion dollar global pharmaceutical company. In the late 1990s, patents on five of its best-selling drugs were nearing expiration. JA51 (¶76).[2] Merck's best prospect for replacing the revenue it expected to lose was Vioxx, a new type of non-steroidal anti-inflammatory drug ("NSAID") known as a Cox-2 inhibitor. Vioxx promised to provide the same pain relief as traditional NSAIDs (*e.g.*, aspirin, ibuprofen, and naproxen) with significantly reduced

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[2] The Fourth Amended Complaint was the operative complaint in the Third Circuit. JA20-263. After additional details of Merck's fraud emerged and the case was remanded, respondents filed, with Merck's consent, a Fifth Amended Complaint on March 10, 2009. The Fifth Amended Complaint is excerpted at JA270-90; the full version is available on PACER.

gastrointestinal side effects. Market watchers viewed Vioxx as critical to Merck's future. JA52 (¶77).

Vioxx received Food and Drug Administration ("FDA") approval in May 1999. JA60 (¶94). Nothing in the Precautions, Warnings, or Contraindications sections of Vioxx's product label suggested that it posed cardiovascular risks. Vioxx quickly met expectations, generating more than $2 billion in sales in its first year.

On March 27, 2000, Merck announced the preliminary results from VIGOR. Merck's press release reported that Vioxx users suffered significantly fewer gastrointestinal problems than naproxen users, but significantly more thromboembolic (*i.e.*, resulting from blood vessel blockage from clotting) events. The press release described these cardiovascular results as "consistent with Naproxen's ability to block platelet aggregation," adding: "VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effect." JA83 (¶143). Merck's press release stated both that this benign explanation for VIGOR's results was not based on "any clinical studies of naproxen" and 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." JA291, 293.

The financial and medical communities immediately understood that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx increased the risk of heart attacks. *See, e.g.*, JA547 (JP Morgan: "it is impossible to determine if Vioxx patients had an in-

creased risk of suffering heart attacks, or if naproxen patients had a decreased risk"). Most, however, accepted the hypothesis as the best explanation for VIGOR's results, and no one questioned that Merck genuinely believed the hypothesis or had a reasonable basis for it. JA84, 94 (¶¶145, 163). Thereafter, Merck continued promoting the naproxen hypothesis as the "likely" explanation for VIGOR's increased incidence of cardiac events among Vioxx users (Br. 4) and repeatedly claimed it had non-public internal data showing "no difference in the incidence of cardiovascular events . . . among patients taking Vioxx, other NSAIDs and placebo." JA96 (¶166).

On February 8, 2001, a senior Merck scientist reiterated Merck's belief in the naproxen hypothesis at public FDA Arthritis Advisory Committee ("AAC") hearings on Merck's request for a revised drug label providing that Vioxx caused fewer gastrointestinal problems than traditional NSAIDs. 5thAC[3] ¶276. The AAC Chairperson, while noting the naproxen hypothesis remained unproven, stated that "[d]ifferences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx." JA403; *see also* JA394. Contemporaneous news articles reported those statements. JA394, 403.

In August 2001, the *Journal of the American Medical Association* ("*JAMA*") published an article discussing possible cardiovascular risks associated with Cox-2 inhibitors, including Vioxx. JA319-38. It stated that, "[given] the evidence for an antiplatelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR

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[3] Corrected Consol. Fifth Am. Class Action Compl. (filed Mar. 10, 2009) ("5thAC").

was due to a benefit from naproxen or to a prothrombotic effect from [Vioxx]," JA327, and that a clinical trial should be conducted to assess possible cardiovascular risks of Cox-2 inhibitors, JA331. Just before it was published, Merck publicly stated: "We already have additional data beyond what [*JAMA*] cite[s], and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." JA119 (¶214).

On September 21, 2001, FDA's website posted a warning letter that the agency's Division of Drug Marketing, Advertising, and Communications ("DDMAC") had sent to Merck four days earlier regarding certain Vioxx marketing activities. JA339-54. The letter primarily concerned statements made by a Merck consultant during teleconferences with doctors' groups in June 2001 and by Merck sales representatives at exhibit booths at two June 2001 pharmacist conventions. It stated that those promotional activities violated FDA-specific statutes and regulations that characterize as "false, lacking in fair balance, or otherwise misleading" any drug company promotional material that fails to disclose all of a drug's potential risks – even if those risks are already common knowledge. JA339 (citing 21 U.S.C. §§331, 352); *see* 21 C.F.R. §202.1(e)(5)(ii).

DDMAC's letter acknowledged that the naproxen hypothesis provided a "reasonable" explanation of VIGOR's results, but criticized those specific Merck promotions because they "fail[ed] to disclose that [the naproxen hypothesis] is hypothetical." JA340. DDMAC directed Merck to send a letter to the approximately 100 doctors and 1,300 pharmacists who attended the events at issue to confirm that the naproxen hypothesis remained unproven and that another possi-

ble explanation for VIGOR was that Vioxx raised the risk of cardiovascular events. JA353.

Following initial reports about DDMAC's letter, Merck's stock price declined by approximately $3 over two trading days – a brief dip one analyst attributed to market "[n]oise." JA626.[4] By September 25, 2001, leading financial analysts reported that DDMAC's letter contained no new information. A Dain Rauscher analyst wrote that the omissions flagged by DDMAC "likely" are "already common knowledge in the medical community." JA618. A Lehman report added: "Warning letters of this nature are certainly not unusual and in fact [are] almost a staple of the pharmaceutical industry today" – and characterized DDMAC as merely charging Merck with violating technical FDA drug marketing rules. JA624.

No analyst downgraded Merck's stock; most retained "buy" or "strong buy" ratings on Merck and maintained price targets well above Merck's then-current stock price. JA809-11. By September 27, 2001, four trading days after DDMAC's letter became public, Merck's stock price closed higher ($62.66) than it did on the date the letter was posted ($62.18); it continued to track the S&P's pharmaceutical index for months thereafter. JA832.

Between May 29, 2001, and October 1, 2001, four personal-injury complaints were filed alleging – based solely on VIGOR's results, *JAMA*'s article, and

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[4] "Noise" in this context is commonly defined as trading (typically by less sophisticated investors) done in the absence of meaningful new information. *See, e.g.*, Thomas Lee Hazen, *The Short-Term/Long-Term Dichotomy and Investment Theory: Implications for Securities Market Regulation and for Corporate Law*, 70 N.C. L. Rev. 137, 157 (1991).

DDMAC's letter – that Merck had failed directly to warn Vioxx users on an individual basis of the drug's potential risks. JA868-958. In SEC filings, Merck repeatedly stated that those suits were "completely without merit," JA126 (¶227), and were "considered normal to its business."[5]

On October 9, 2001, *The New York Times* ("*NYT*") published an article quoting petitioner Edward Scolnick, Merck's Chief Scientific Officer. Addressing possible explanations for VIGOR's results, Scolnick reiterated that "the likeliest interpretation of the data is that naproxen lowered the thromboembolic event rate" and said Merck had "found no evidence that Vioxx increased the risk of heart attacks." 5thAC ¶159.

In April 2002, FDA approved (1) Merck's proposed product label regarding Vioxx's gastrointestinal safety, and (2) expanded Vioxx's approved indications to include treatment for rheumatoid arthritis. JA145 (¶256). The new label also, for the first time, addressed Vioxx's cardiovascular safety profile in the "Precautions" section, stating that the "significance of the cardiovascular findings" from three studies (including VIGOR) "is unknown." JA140 (¶251). One week later, a Merck spokesperson repeated to analysts Merck's "belief that the effect seen in VIGOR were the results of the anti-platelet effect of naproxen." JA148 (¶258). Investors continued to purchase Merck stock – including many in the class who had not owned Merck shares prior to November 2001.

On October 30, 2003, the *WSJ* reported the results of a large-scale, observational study of 50,000

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[5] *See, e.g.*, Merck & Co., Form 10-Q, at 14 (filed Nov. 13, 2002).

Medicare patients performed by Harvard University's Brigham and Women's Hospital ("the Harvard Study"). The study, funded by an unrestricted Merck grant, found that Vioxx users had a significantly greater risk of heart attack than Celebrex users and an elevated risk compared to users who took other NSAIDs or no painkillers. JA164 (¶290). Merck immediately criticized the study's methodology and conclusions, and it reiterated its own purportedly reliable clinical trial data as finding "no significant difference" between Vioxx and placebo. JA165-66 (¶¶291, 293).

A week later, on November 6, 2003, an investor filed the first securities-fraud complaint against Merck. Meanwhile, Vioxx continued to generate billions in revenues for Merck – more than $2.5 billion annually in 2002 and 2003. JA55 (¶85).

On September 30, 2004, Merck abruptly withdrew Vioxx from the market after an independent safety monitoring board stopped a Vioxx trial due to "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." JA182 (¶321). Merck's shares fell almost 27% on that news – their greatest one-day percentage price decline in over a decade. JA856.

*2. Non-public information subsequently disclosed*

On November 1, 2004, a *WSJ* article disclosed previously secret internal Merck emails demonstrating that Merck had long harbored serious concerns that Vioxx was prothrombotic and viewed VIGOR's results as confirming those fears. JA189-97 (¶¶332-334). Merck shares plummeted another 10%. As one analyst reported: "the situation might not be as innocent as we thought." JA198 (¶337).

Additional details of Merck's fraud have since emerged. Those previously undisclosed facts –

brought to light through investigative newspaper articles, congressional hearings, and unsealed documents discovered in product liability lawsuits – further revealed how Merck (a) had long feared that Vioxx caused cardiovascular problems; (b) intentionally manipulated its reported research to mask Vioxx's harmful effects; and (c) fraudulently schemed to promote the naproxen hypothesis to avoid jeopardizing Vioxx's lucrative revenue stream.

Indeed, three years before Vioxx received FDA approval, Merck learned of data suggesting that Vioxx might lead to increased blood clotting and raise the risk of thrombotic events, as well as other non-public information indicating potential prothrombotic attributes of Vioxx. 5thAC ¶¶98-103, 111-113. Merck had planned to begin a large-scale clinical trial soon comparing Vioxx to naproxen. However, as one Merck scientist wrote, if Merck proceeded with the proposed trial, Vioxx users would suffer "more thrombotic events," which would "kill the drug." *Id.* ¶105. Another top Merck scientist, petitioner Alise Reicin, added: "the possibility of increased CV [cardiovascular] events is of great concern." *Id.* ¶107. Reicin instead proposed that Merck exclude from the trial patients at high risk of suffering cardiovascular problems, stating: "This may decrease the CV event rate so that a difference between the [Vioxx and naproxen] groups would not be evident." *Id.* ¶108. Instead, Merck cancelled the trial.

In February 1998, an internal Merck analysis showed that women taking Vioxx had a statistically significant 216% greater risk of adverse cardiovascular events, while men had a 28% increased risk. Merck concealed those adverse data, took steps to avoid developing further evidence that Vioxx might

cause cardiovascular problems, and continued pushing for FDA approval. *Id.* ¶¶117-122.

By early 1999, Pfizer had begun a large-scale trial to establish that Celebrex caused fewer serious gastrointestinal problems than traditional NSAIDs. The competitive threat from Celebrex forced Merck to proceed with VIGOR (the large-scale trial it cancelled years earlier). *Id.* ¶¶125-126.

In an attempt to mask any prothrombotic properties of Vioxx, Merck excluded from VIGOR patients at higher risk of suffering adverse cardiovascular events – exactly as petitioner Reicin had suggested years earlier. *Id.* ¶127. Nevertheless, Vioxx users still suffered significantly more adverse cardiovascular events than naproxen users. Internal emails show how those results confirmed to Merck – as petitioner Scolnick stated in one such email – that the cardiovascular events among Vioxx users "***are clearly there***" and that "***it is mechanism based as we worried it was***." *Id.* ¶¶137-138.

Before publicly announcing VIGOR's results, Merck scrambled to devise a plausible alternative explanation for its cardiovascular data. Despite their true beliefs and possession of significant contrary non-public information, *id.* ¶142, Merck concocted, then widely promoted, the naproxen hypothesis and continued to cover up subsequently developed adverse information, *id.* ¶¶160-193.

According to its August 3, 2009 Form 10-Q, Merck remains under criminal investigation by various governmental authorities in connection with Vioxx.

### C. District Court Proceedings

On November 6, 2003, the initial securities-fraud action was filed, with later complaints consolidated

in the District of New Jersey. The Fourth Amended Complaint was filed in June 2005, which substantially elaborated on these earlier complaints. Merck moved to dismiss.

The district court dismissed respondents' §10(b) claims as time-barred, holding that respondents were on inquiry notice more than two years before the first action was filed. The court interpreted respondents' complaint to allege that Merck's fraud involved concealing that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx caused adverse cardiovascular events. The court held that respondents were on "inquiry notice" of those facts no later than the October 9, 2001 *NYT* article, when Scolnick acknowledged that one explanation for VIGOR's results was that Vioxx might cause heart attacks; it also relied on DDMAC's September 2001 letter. Pet. App. 85a-86a.

Finding that "inquiry notice" existed as of October 9, 2001, the district court held that the limitations period ran from that date. *Id.* at 94a, 97a-98a.

**D. The Third Circuit's Decision**

The Third Circuit reversed, finding that the district court had mischaracterized respondents' claims and that "inquiry notice" occurred not earlier than October 30, 2003, when the *WSJ* reported the Harvard Study.

The Third Circuit found that respondents had *not* alleged that Merck misrepresented whether Vioxx might cause heart attacks, Pet. App. 33a-35a, noting that the possibility had been obvious from Merck's first announcement of VIGOR's results, *id.* at 39a-40a. The court read the complaint to allege that Merck misrepresented its *belief* in the naproxen hypothesis – *i.e.*, that Merck "did not hold th[e] opinions

or beliefs in earnest." *Id.* at 33a (citing *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095 (1991)). It then found that, as of November 6, 2001, a reasonable investor would have had no reason to suspect that Merck's endorsement of the naproxen hypothesis falsely represented its opinion. *Id.* at 46a ("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.").

The Third Circuit concluded that the public documents on which the district court relied showed only that the hypothesis was unproven – a fact "Merck had long acknowledged and . . . the market had incorporated." *Id.* at 43a. The court concluded that neither DDMAC's letter nor the October 9, 2001 *NYT* article provided investors with new information or "charge[d] that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis." *Id.* Accordingly, those documents provided no "storm warnings" that Merck falsely represented its opinion on the proper interpretation of VIGOR's results. *Id.*

The Third Circuit observed: "[W]e must not lose focus of the nature of the allegations in [DDMAC's] letter and the scope of the FDA's regulatory authority. . . . [T]he FDA's drug advertising regulations and the securities laws provide wholly different standards with respect to what constitutes a misrepresentation." *Id.* at 41a-42a. The court concluded:

> [T]he 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 [respondents] on

> inquiry notice of actionable misrepresentations under the securities laws. The asserted basis of [respondents'] claims is that Merck defrauded investors by proposing and reasserting the naproxen hypothesis at the same time that it knew the hypothesis was false.

*Id.* at 34a-35a (citation omitted). The court also found the handful of pre-November 2001 consumer lawsuits irrelevant because they did nothing more than "allege[] that Merck failed to provide publicly available information to Vioxx consumers." *Id.* at 45a.

The Third Circuit noted that Merck's stock price remained relatively unchanged through those 2001 developments and determined that the absence of any "significant [price] movement," though not conclusive, indicated that financial markets did not view DDMAC's letter or the October 2001 *NYT* article as providing significant new information. *Id.* at 44a-45a. The court also noted that analysts "continued to maintain their ratings for Merck stock and/or projected increased future revenues" after the purported storm warnings. *Id.* at 45a.

Accordingly, the court concluded that respondents timely filed suit. Judge Roth dissented.

## SUMMARY OF ARGUMENT

**I.** The two-year limitations period for "a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws," 28 U.S.C. §1658(b), begins upon "the discovery of the facts constituting the violation," *id.* §1658(b)(1).

**A.** The "facts constituting" a 1934 Act §10(b) violation are those that establish each of the elements of that violation: falsity, materiality, and scienter. In a case alleging misrepresentation of belief, as here, a misrepresentation must be "a misstatement of the psychological fact of the speaker's belief in what he says" and must "also mislead about the stated subject matter" because of something "false or misleading in what the statement expressly or impliedly declare[s] about its subject." *Virginia Bankshares*, 501 U.S. at 1095-96.

**B.** Although §1658(b)'s unqualified reference to "discovery" would in ordinary usage mean actual discovery, that term can also include constructive discovery. Under established precedent, constructive discovery of a fraud occurs when a reasonable investor would have discovered sufficient facts that, if proved, would establish falsity, materiality, and scienter. Constructive discovery does not include facts that would not or could not have been discovered through reasonable diligence.

**C.** "Inquiry notice" is merely a part of the constructive-discovery analysis. An investor is said to be on "inquiry notice" of fraud if, based on a retrospective analysis of what inquiries a reasonable investor would have made, and what that investor would have learned as a result, it is determined that

such investor would have discovered the facts constituting the violation.

Inquiry notice cannot be established merely by showing an investor had information to put him on his guard; the investor must also have "the means of discover[ing]" the fraud "in his power." *Wood v. Carpenter*, 101 U.S. 135, 141 (1879). Plaintiffs are not chargeable with constructive knowledge of information that defendants keep hidden.

**D.** The context and structure of §1658(b)(1) confirm this reading. The two-year limitations period is juxtaposed with a five-year repose period that protects defendants from indefinite exposure by running from the date of a §10(b) violation, without regard to what investors knew or should have known. The two-year period only bars claims that could and should have been brought earlier and preserves claims of "injured investors who by no conceivable standard of fairness or practicality c[ould] be expected to file suit" earlier. *Lampf*, 501 U.S. at 377-78 (Kennedy, J., dissenting).

**II.** Merck seeks to rewrite §1658(b)(1) so that "information sufficiently suggestive of wrongdoing," Br. 20, starts the limitations period without regard to whether (a) the "wrongdoing" suggests securities fraud or (b) investors should or even could have discovered the facts constituting a §10(b) violation. Merck's standard is contrary to more than a century of this Court's constructive-discovery jurisprudence and benefits those defendants who are best at hiding their fraud.

**A.** Merck's proposed test omits the requirement that the "means of knowledge" must be "accessible" to the fraud victim. *Burke v. Smith*, 83 U.S. (16 Wall.) 390, 401 (1873). Merck relies on numerous cases

from this Court that turn on the ability of a reasonable person to have actually discovered the fraud, but fails to address this fundamental requirement.

**B.** Merck's argument that the limitations period should begin with "information sufficiently suggestive of wrongdoing," Br. 20 (which they define as "inquiry notice," Br. 40), misconstrues inquiry-notice principles and lacks support in precedent. Moreover, it cannot be reconciled with §1658(b)(1)'s plain language: "the facts constituting the violation" are not the same as information that would merely trigger a duty to inquire.

Merck's alternative argument that the limitations period should still begin with "information sufficiently suggestive of wrongdoing," with an extension for an actual diligent inquiry, Br. 43, also ignores §1658(b)(1)'s text. This argument treats §1658(b)(1) as if it contained a statutory deadline that courts might equitably extend through judicially created equitable tolling – a doctrine that is "the exception, not the rule." *Rotella v. Wood*, 528 U.S. 549, 561 (2000). In §1658(b)(1), Congress adopted the opposite approach: "discovery of the facts constituting the violation" is the rule, not the exception. Moreover, Merck's own equitable-tolling and fraudulent-concealment cases measure diligence by what the injured party reasonably should have known.

The only cases supporting Merck's forfeiture approach are recent Second and Third Circuit decisions. The Second Circuit cited no legal support for its recent "rule," and the Third Circuit (based on analysis and policies applicable to RICO, not §10(b)) acknowledged it was departing from the rule followed in other circuits that turn on what reasonable investors would have discovered had they inquired.

**C.** Merck's argument that "hypothetical inquiries about what a reasonably diligent investigation would have entailed" would pose "grave difficulties," Br. 50, is without foundation. Juries and courts, including this Court, routinely resolve questions of what reasonable persons would have done under virtually limitless circumstances, including in the context of traditional constructive-discovery rules. This inquiry will often involve mixed questions of law and fact that are most appropriately left to a jury.

**D.** Merck also argues that scienter is not among the facts constituting a §10(b) violation and that the Third Circuit erred by adopting a contrary rule. Br. 22. However, the Third Circuit adopted no such rule here: it held simply that respondents had no reason even to suspect that Merck's statements of opinion were false until October 2003 at the earliest. This Court can affirm on that basis.

If the Court reaches the issue of whether facts constituting the violation include scienter, it should hold that it does. Scienter is an essential element of a §10(b) violation, and facts giving rise to actual or constructive discovery of scienter are essential to trigger the running of the statute. Merck's argument that scienter is often proved through circumstantial evidence misses the point. Circumstantial facts can provide investors with sufficient basis to conclude that a defendant's misconduct was committed with scienter; but, where no such facts exist, scienter cannot be inferred, and the statute does not run.

**E.** Merck argues that by 2002 there was a settled rule that the limitations period should commence with "information sufficiently suggestive of wrongdoing" and that Congress "ratified" that purported rule in enacting §1658(b)(1). As Merck's own petition

to this Court argued, however, there was no such consensus in 2002.

**III.A.** The Third Circuit correctly held that, as of November 6, 2001, respondents had no reason to suspect Merck's statements of belief in the naproxen hypothesis were even false. As of that date, no publicly available information suggested that Merck's stated belief in the naproxen hypothesis was not sincerely held or lacked reasonable basis. The naproxen hypothesis's validity was publicly debated, but nothing in the public domain would have led a reasonable investor to suspect that Merck was promoting that hypothesis as part of a fraud.

DDMAC's September 2001 letter did not suggest that the naproxen hypothesis lacked reasonable basis or that Merck did not genuinely believe in it. To the contrary, it stated, as had members of FDA's AAC previously, that the hypothesis was a reasonable explanation of VIGOR's results. The letter chastised Merck for violating FDA marketing regulations that required every Vioxx promotional statement to consumers and medical professionals to repeat that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx increased the risk of cardiovascular events. That alternate explanation was always well-known to financial markets, and thus a reasonable investor would have found nothing new or material in the letter. Likewise, the consumer tort lawsuits filed before November 6, 2001, provided no new material information to investors.

**B.** Even assuming arguendo that respondents should reasonably have suspected fraud before November 6, 2001, §1658(b)(1)'s two-year discovery period could not have begun to run because investors

lacked the means to discover the fraud through reasonable inquiry. Merck has never identified anything that its investors should or could have done to discover its fraud before that date. The previously available public information provided no facts upon which a reasonable investor would have concluded that Merck violated §10(b). The critical facts and relevant documents were under Merck's exclusive control.

Accordingly, the court below correctly rejected Merck's contention that, as a matter of law, the limitations period was triggered more than two years before respondents filed the first securities-fraud complaint.

## ARGUMENT

### I. THE LIMITATIONS PERIOD BEGINS WITH DISCOVERY OF THE ELEMENTS OF A VIOLATION, INCLUDING SCIENTER

Section 1658(b)(1)'s two-year limitations period begins with "the discovery of the facts constituting the violation." 28 U.S.C. §1658(b)(1). This Court interprets §1658(b)(1) by assuming "the ordinary meaning of that language accurately expresses the legislative purpose." *Gross v. FBL Fin. Servs., Inc.*, 129 S. Ct. 2343, 2350 (2009) (internal quotations omitted).

#### A. The "Violation" Referenced In §1658(b)(1) Is A Violation Of §10(b)

##### *1. The elements of a §10(b) violation are well-established*

All parties agree that the "violation" here is a violation of §10(b) of the 1934 Act and SEC Rule 10b-5 promulgated thereunder. In a misrepresentation case, §10(b) is violated when a defendant has (1) made a misrepresentation (2) that is material,

(3) with scienter, (4) in connection with the purchase or sale of securities. *See* 17 C.F.R. §240.10b-5(b) (prohibiting, *inter alia*, "any *untrue statement* of a *material* fact") (emphases added); *Aaron v. SEC*, 446 U.S. 680 (1980) (holding that *scienter* is an essential element of a violation). Investors therefore have not "discover[ed]" enough "facts [to] constitut[e] [a] violation" unless each of those elements is present.[6]

Although the substantive content of the falsity, materiality, and scienter elements of a §10(b) violation is well-settled, a brief summary of those elements helps to place in context the parties' dispute over *when* investors should have discovered Merck's §10(b) violation.

*First*, the federal securities laws recognize that two types of misrepresentations can violate §10(b): misrepresentations of historical or current facts, such as a company's reported earnings, and misrepresentations of "reasons, opinions, or beliefs." *Virginia Bankshares*, 501 U.S. at 1091. Statements of opinion are "factual in two senses": they are statements that the speaker does "hold the belief stated" and "statements about the subject matter of the reason or belief expressed." *Id.* at 1092. Thus, in a case alleging misrepresentation of belief, as here, it must be "a misstatement of the psychological fact of the speaker's belief in what he says" and must "also mislead about the stated subject matter," *id.* at 1095,

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[6] Under Rule 10b-5, a private investor must also prove reliance, economic loss, and loss causation. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 768 (2008). Because there could not have been discovery of the elements of a §10(b) *violation*, the Court need not decide whether §1658(b) requires separate discovery of these additional elements of a private *cause of action* to trigger the limitations period.

because it lacks the "factual basis that justifies [the opinion] as accurate," *id.* at 1093, or is otherwise "false or misleading in what the statement expressly or impliedly declare[s] about its subject," *id.* at 1095-96.

*Second*, only "material" misstatements violate §10(b), *i.e.*, misstatements that would be "viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32 (internal quotations omitted). *Third*, "scienter is a necessary element of a violation of §10(b) and Rule 10b-5." *Aaron*, 446 U.S. at 695. Investors lacking reasonable basis to believe that a defendant acted with scienter have not discovered a §10(b) violation.

*2. The "facts constituting" a violation are those that establish its elements*

The phrase "facts constituting [a] violation" derives from longstanding ordinary and legal usage of similar language and indicates the appropriate contents of a pleading seeking judicial relief. In ordinary usage, to "constitute" a thing is "to make [it] up, as being the constitutive element or elements." *Webster's New International Dictionary of the English Language* 571-72 (2d ed. 1953). The "facts constituting [a] violation" are thus most naturally its elements. Judicial usage comports with that ordinary meaning. For example, many "constitutional protections turn on determining which facts constitute the 'crime' – that is, which facts are the 'elements' or 'ingredients' of a crime." *Apprendi v. New Jersey*, 530 U.S. 466, 500 (2000) (Thomas, J., concurring).

The language the 1934 Congress enacted in §9(e) was not new. The phrase "facts constituting" appeared in connection with the facts required for

proof at trial, *see, e.g.*, *Harding v. Robinson*, 166 P. 808, 810 (Cal. 1917); criminal indictments, *see, e.g.*, *Brown v. State*, 42 S.E. 795, 796 (Ga. 1902); and pleading, including the "highly influential" pleading model of the day, New York's Field Code of 1848, which required litigants to provide a "statement of the facts constituting the cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 574 (2007) (quoting Field Code of 1848, ch. 379, §120(2), 1848 N.Y. Laws pp. 497, 521)[7]; *see also* Fed. R. Crim. P. 7(c)(1) (requiring information or indictment to contain "the essential facts constituting the offense charged").

In fraud actions, the courts commonly interpreted the phrase "facts constituting" as those facts that, if proved, would establish all elements of a fraud, including scienter. *See, e.g.*, *Martin v. Smith*, 16 F. Cas. 896, 901 (C.C.D. Mo. 1870) ("If a party knows the facts constituting the fraud, he knows the transaction to be fraudulent. It is not enough simply that he is aware of the fact of the transfer, but he must know 'the facts' which make that transfer fraudulent.") (cited with approval in *Wood*, 101 U.S. at 141).[8] For limitations periods triggered by discovery of "'the facts constituting the fraud,'" courts long have held that "the limitation begins to run as

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[7] The Federal Rules of Civil Procedure were promulgated in 1938.

[8] *See also, e.g.*, *Guy v. Blue*, 45 N.E. 1052, 1053 (Ind. 1897) (in order to show "facts constituting [a] fraud," the "intention to deceive must appear"); *West Virginia Hotel Corp. v. W.C. Foster Co.*, 132 So. 842, 846 (Fla. 1931) (the "essential facts constituting the fraud" must give a "real foundation . . . for the charge of fraud"); *Harding*, 166 P. at 810 ("The material ingredient of actual fraud is the fraudulent intent, and this must be charged as one of the facts constituting the fraud.").

against the plaintiff when he has knowledge of facts which would have impressed a reasonable man with the belief that the transaction was fraudulent." *Martin*, 16 F. Cas. at 902; *see also Higgins v. Crouse*, 42 N.E. 6, 7 (N.Y. 1895) (contrasting the "suspicion" that "suggest[s] the need of an inquiry" with the "decided inference of fraud" that amounts to discovery); 2 Calvin W. Corman, *Limitation of Actions* §11.5.7, at 203 (1991) ("Suspicion that a fraud has been perpetrated . . . should not be equated with knowledge of facts that point to the actual existence of fraud.").

Therefore, as used in §1658(b)(1), the most natural reading of "facts constituting" refers to those facts that, if proved, would establish that the defendant violated §10(b), *i.e.*, made a material misrepresentation or omission with the intent to deceive.

### B. "Discovery" Of Facts Occurs When Those Facts Were Or Should Have Been Known

In ordinary usage, "discovery" occurs when one has "f[ound] out or ascertain[ed] the existence of something previously unknown or unrecognized," *Webster's Second* at 745 – that is, when one has acquired actual knowledge of a fact. A plain reading of §1658(b)(1), therefore, would start the limitations period with an investor's *actual* discovery of the elements of Rule 10b-5 violation. Further, a comparison of §1658(b)(1) (and its predecessor, §9(e)) to 1933 Act §13 shows that Congress knew how to create a limitations period that ran after "discovery should have been made by the exercise of reasonable diligence," 15 U.S.C. §77m, when it meant to do so.

Although the Court could affirm on such a plain reading of the statute, the word "discovery" also can be construed as incorporating a principle of *constructive* discovery through "accumulated . . . legal tradi-

tion and meaning." *Morissette v. United States*, 342 U.S. 246, 263 (1952). By 1934, when Congress originally enacted §9(e), many state statutes provided for commencement of a limitations period for fraud with the "discovery . . . of the fact constituting the fraud." John P. Dawson, *Undiscovered Fraud and Statutes of Limitation*, 31 Mich. L. Rev. 591, 591 n.1 (1933) (listing 32 states). The word "discovery" was "everywhere taken to mean something less than *actual* discovery of the defendant's wrong: the wrong is 'discovered' at the point where the facts *could have been ascertained* by using *reasonable* diligence." *Id.* at 619 & n.77 (emphases added) (collecting cases).[9]

This Court's cases also had recognized a constructive-discovery principle well before 1934 applying the traditional equitable discovery rule that, "where relief is asked on the ground of actual fraud, especially if such fraud has been concealed, time will not run in favor of the defendant until the discovery of the fraud, or until, with reasonable diligence, it might have been discovered." *Kirby v. Lake Shore & M.S. Ry. Co.*, 120 U.S. 130, 136 (1887).[10] That rule has

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[9] *See also, e.g., Silva v. Menderson*, 17 P.2d 809, 810 (Ariz. 1933) ("This statute is not peculiar to Arizona. Its counterpart exists in many of the states . . . . [I]f the facts and circumstances were such *as in the exercise of reasonable care and diligence he should have discovered the fraud*, he is deemed to have notice."); *Duxbury v. Boice*, 72 N.W. 838, 839-40 (Minn. 1897) (same; also observing similarity to other statutes).

[10] *See also Amy v. City of Watertown*, 130 U.S. 320, 324 (1889) ("The courts of equity, . . . from an early day, held that where one person has been injured by the fraud of another, and the facts constituting such fraud do not come to the knowledge of the person injured until some time afterwards, the statute will not commence to run until the discovery of those facts, or until by reasonable diligence they might have been discovered."); *Duxbury*, 72 N.W. at 839 (quoting the English statute of 3 & 4

continued through the present. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 30 (2001) (under a discovery rule, limitations period begins running when "a reasonable person in [the plaintiff's] position would have learned of the [fact to be discovered] in the exercise of due diligence").

The term "discovery," however, does not extend to encompass information an investor neither knew nor would have learned through reasonable diligence. *See id.* (quoting 2 Corman §11.1.6, at 164: "It is obviously unreasonable to charge the plaintiff with failure to search for [a] missing element of [a] cause of action if such element would not have been revealed by such search."). Accordingly, no plausible interpretation of §1658 would permit the limitations period to commence at a time when investors neither knew nor should have known facts constituting a §10(b) violation.

### C. "Inquiry Notice," Properly Understood, Is Only A Part Of The Doctrine Of Constructive Discovery

The principle of "inquiry notice" posits that a party who has enough information "'to excite attention and put the party on his guard and call for inquiry'" is considered on "'notice of every thing to which such inquiry might have led.'" *Wood*, 101 U.S. at 141 (quoting *Kennedy v. Greene*, 3 Myl. & K. 722 (Ch. 1834)). Similarly, in *Higgins*, the court interpreted the phrase "discovery . . . of the facts constituting the fraud" in New York's statute of limitations, explaining that one who "know[s] sufficient [facts] to fairly

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Wm. IV, c. 27, §26, and holding that a claim is "'deemed to have first accrued *at and not before* the time at which such fraud shall, or with reasonable diligence might have been, first known or discovered'") (emphasis added).

arouse suspicion" in a case where "reasonable and natural action would reveal the truth and disclose the fraud" will be charged with "the knowledge which he ought to have had, and would have had if he had done his duty." 42 N.E. at 7.

Inquiry notice is thus part of, not separate from, a retrospective constructive-discovery analysis that focuses on what investors should have known.[11] Investors exercising reasonable diligence to protect their rights will occasionally obtain information suggesting possible fraud. If investors have "means of knowledge accessible" for obtaining more information about possible fraud, reasonable diligence then requires use of those means. *Burke*, 83 U.S. at 401. If reasonable further inquiry would reveal additional information of fraud, then the investor will be "held to have known" that information. *Wood*, 101 U.S. at 141. At every stage of the analysis, however, the question remains what "a reasonable person . . . *would have learned* . . . in the exercise of due diligence." *TRW*, 534 U.S. at 30 (inquiry notice applies "only if" reasonable person would have learned relevant facts) (emphasis added).

*1. Inquiry notice begins with a reason to inquire about fraud*

In securities cases, courts colorfully have referred to facts that would "alert a reasonable investor to the possibility of fraudulent statements or omissions

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[11] For example, "investors are presumed to have read prospectuses, quarterly reports, and other information relating to their investments," whether or not they had a specific reason to inquire. *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 252 (3d Cir. 2001). That type of information usually provides the predicate for asking whether an investor should then have inquired further. *See id.*

in his securities transaction" – thereby triggering a duty to inquire – as "storm warnings." *E.g.*, *Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988). Merck does not quarrel with that general statement of the standard, *see* Br. 21 & n.4, and neither do respondents. That duty to inquire ordinarily marks the beginning point for the court's retrospective constructive-knowledge analysis.

Importantly, a judicial finding that an investor should have made inquiry is a legal conclusion that the failure to inquire constituted negligence. *See, e.g.*, *Foster v. Mansfield, C. & L.M.R.R. Co.*, 146 U.S. 88, 99-100 (1892) (question is whether "negligence is imputable to [plaintiff] for failing to inform himself of his rights"); *cf. Higgins*, 42 N.E. at 7 (party "is not negligent for failing to enter upon an investigation which no fact within his knowledge indicates to be necessary or prudent"). Dismissal on the pleadings on an inquiry notice theory without any fact-findings, therefore, represents a judgment that the plaintiffs have pleaded facts establishing their own negligence as a matter of law. That should be a heavy burden for any defendant to establish, and Merck cannot meet it in this case.[12]

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[12] Absent clear-cut circumstances, most courts reserve for a jury issues of when "discovery of facts constituting the violation" should be deemed to have occurred. *See Gurley v. Documation Inc.*, 674 F.2d 253, 259 (4th Cir. 1982); *Kennedy v. Tallant*, 710 F.2d 711, 716 (11th Cir. 1983); *see also Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 425-26 (2d Cir. 2008) (citing 5 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* §1226 (3d ed. 2004), for the proposition that, because a time-bar is an affirmative defense under federal law, a complaint can be dismissed on limitations grounds only for a defect that appears on its face).

*2. Inquiry notice requires the means of discovering the facts constituting the violation*

Information calling for inquiry, however, is not sufficient by itself to commence the limitations period. Even once a party learns facts "sufficient to put her on inquiry, she can only be charged with knowledge of the facts which she might have learned by inquiry." *Indiana & I.C. Ry. Co. v. Sprague*, 103 U.S. 756, 762 (1881); *see also Wood*, 101 U.S. at 141 (plaintiff must have "the means of discovery in his power" to be on inquiry notice).[13] Prior to 1934, states that adopted statutes running the limitations period from "discovery" of the facts constituting the fraud uniformly offered similar interpretations. *See* 2 H. Wood, *Limitations of Actions* §276b(12), at 1403-05 (4th ed. 1916).[14] Seventy-five years after Congress adopted 1934 Act §9(e)'s "discovery rule," that time-honored principle remains unchanged. *See TRW*, 534 U.S. at 30 ("The duty of inquiry having arisen, plaintiff is charged with whatever knowledge an inquiry would have revealed.") (internal quotations omitted).

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[13] *See also Burke*, 83 U.S. at 401 (plaintiff must be "put upon inquiry with the means of knowledge accessible to him"); *Kirby*, 120 U.S. at 139 (quoting *Burke*); *Oliver v. Piatt*, 44 U.S. (3 How.) 333, 410 (1845) (purchaser who was "positively put upon inquiry" with regard to validity of title also had "most ample means of knowing the nature and character and extent of the title").

[14] *E.g., Consolidated Reservoir & Power Co. v. Scarborough*, 16 P.2d 268, 269 (Cal. 1932); *Richardson v. Mounce*, 19 S.C. 477, 1883 WL 4905, at *4 (S.C. 1883); *O'Dell v. Burnham*, 21 N.W. 635, 639 (Wis. 1884); *Parker v. Kuhn*, 32 N.W. 74, 82 (Neb. 1887); *Brown v. Irving-Pitt Mfg. Co.*, 292 S.W. 1023, 1025 (Mo. 1927); *Ray v. Divers*, 264 P. 673, 675 (Mont. 1928).

Accordingly, if information that led to a duty to inquire by investors would not lead to discovery of facts from which a reasonable person would infer fraud, inquiry notice of "the facts constituting the violation" has not occurred. *Wood*, 101 U.S. at 141 (inquiry notice applies when party has "sufficient information to lead him to a [relevant] fact") (internal quotations omitted). For example, if defendants have successfully concealed the facts necessary to discover "facts constituting" the fraud, or provide legitimate explanations for the circumstances that excited inquiry, a court looking backward will not conclude that the plaintiff was on inquiry notice of the true, unavailable facts. *See Sprague*, 103 U.S. at 763 (refusing to impute bad faith to bond investor because any further inquiry made "would have afforded a most satisfactory explanation").

This Court's cases illustrate what sort of inquiry is reasonable. Commonly, plaintiffs are charged with reviewing documents to which they have ready access. *See Burke*, 83 U.S. at 401 (reasonable for creditors with access to corporate records to inspect privately held company's books, which would have uncovered the alleged fraud).[15] Similarly, plaintiffs may be charged with knowledge of readily accessible public records and proceedings. *See Wood*, 101 U.S. at 139-40.[16] Plaintiffs also may be charged with

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[15] *See also Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) (Posner, J.) (applying an inquiry-notice analysis where "[all necessary information] was in documents that were in the possession of the victim itself"); *Prentiss v. McWhirter*, 63 F.2d 712, 714 (9th Cir. 1933) (construing California's statutory discovery rule).

[16] *See also Redd v. Brun*, 157 F. 190, 194 (8th Cir. 1907) (finding laches where allegedly fraudulent deeds were "spread upon the public records").

knowledge obtainable from readily accessible and identifiable third parties. *See, e.g., Foster*, 146 U.S. at 100 (reasonable to interview dissident directors who protested allegedly fraudulent conduct); *Wood*, 101 U.S. at 141 (reasonable to confirm with third parties whether funds intended for them had been diverted).

Plaintiffs are not, however, charged with knowing facts exclusively within a defendant's control. Merck cites no case where this Court has presumed that plaintiffs would be able to uncover such facts, and it would be inconsistent with the universal rule that the "means of discovery" must be in the *plaintiff's* hands. *Wood*, 101 U.S. at 141; *see Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1997) (dismissing as not "serious" suggestions that plaintiffs "should have hired a lawyer to investigate, called their broker, or called Medco").[17]

In sum, plaintiffs are not deemed to have "discover[ed] the facts constituting the violation" when they neither could nor should have known them through reasonable diligence. When the facts constituting a violation are unavailable, the fraud could not have been discovered, and the two-year limitations period is not triggered.

### D. Statutory Structure Confirms A Focus On What Was Or Should Have Been Known

The context and structure of §1658(b)(1) confirm that Congress intended "discovery of the facts consti-

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[17] *See also Fujisawa*, 115 F.3d at 1335 (in applying inquiry-notice doctrine, court should "bear[] in mind that before [the plaintiff] files his suit he will not have the aid of compulsory process"); *Cunningham v. Pettigrew*, 169 F. 335, 343 (8th Cir. 1909) (declining to assume that defendants would "voluntarily give self-inculpating evidence").

tuting the violation" of §10(b) to be the date on which an investor knew or should have known of facts establishing each element of the violation. Section 1658(b)(1)'s two-year limitations period appears alongside a five-year repose period established by §1658(b)(2). That five-year period runs from the date of the "violation" itself (which, as Merck agrees (at 29-30), is the date of the material misstatement made with scienter). A resourceful defendant can thus conceal the facts constituting its fraud for a sufficient time that a reasonably diligent plaintiff would be time-barred. To do so, however, the defendant must wait five years, not two.

A statute of limitations that incorporates the discovery rule aims "to ensure a fair balance between protecting the legitimate interests of aggrieved investors, yet preventing stale claims." *Lampf*, 501 U.S. at 378 (Kennedy, J., dissenting). It preserves the claims of "injured investors who by no conceivable standard of fairness or practicality can be expected to file suit" earlier than they did. *Id.* at 377. A statute of repose, by contrast, represents the legislature's judgment that, after the repose period, "important considerations of fairness" to defendants, such as likely loss of evidence, outweigh even the loss of meritorious claims through no fault of a plaintiff. *Id.* at 378.

Congress's inclusion of both types of provisions in §1658(b) (and, earlier, in §9) shows the balance it struck. A claim is barred by the two-year period only if it could and should have been brought earlier. A claim may be barred by the five-year period regardless of when it could have been brought, to eliminate the possibility that claims would persist indefinitely because a plaintiff never learns of them. Merck's

extensive discussion of the evils of stale claims and the need to encourage greater diligence – even at the "cost" of foreclosing fraudulently concealed meritorious claims (Br. 32) – nowhere addresses §1658(b)(2) or its plain implication that Congress considered and articulated the circumstances where a truly aggrieved and diligent plaintiff could not recover. This Court should reject Merck's invitation to obstruct the objectives Congress sought to achieve.

## II. NEITHER TEXT NOR PRECEDENT SUPPORTS MERCK'S INVENTED STANDARD

Merck asks this Court to redraw the line between the limitations and repose periods in a manner inconsistent with the statute's plain text, which nowhere suggests that the statute begins before the discovery of facts constituting a violation of §10(b). Merck's proffered rule would require every investor to launch an investigation of unspecified content, cost, and duration of even publicly traded (and widely scrutinized) companies based on "a quantum of information sufficiently suggestive of wrongdoing." Br. 20. That rule would impute discovery of a §10(b) violation to investors without any showing that they should or even could have discovered the facts constituting the violation. Br. 42-43.

Merck maintains that, while its public statements promoting the validity of the naproxen hypothesis were persuading doctors to write billions of dollars in Vioxx prescriptions, investors all along should have known better than medical professionals and disbelieved the very representations that supported Merck's lucrative sales of its blockbuster drug. Merck's rule thus most benefits those who are best at hiding their fraud. More than a century ago, this Court rejected such an approach, refusing to read a

statute of limitations for fraud so as to "make the law which was designed to prevent fraud the means by which it is made successful and secure." *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 349 (1875). This Court should do the same here.

### A. Inquiry Notice Does Not Exist Without Means To Inquire

Merck claims that inquiry notice exists when "a plaintiff possesses a quantum of information sufficiently suggestive of wrongdoing that he should conduct a further inquiry to confirm the existence of his claim." Br. 20. That statement lacks grounding in this Court's cases, which define inquiry notice as attaching only after a plaintiff has been "put upon inquiry *with the means of knowledge accessible to him*." *Burke*, 83 U.S. at 401 (emphasis added); *see supra* pp. 30-31 & n.13. Where an investor could not have discovered the fraud, penalizing the failure to engage in an objectively futile inquiry and marking the date when "inquiry" should have occurred make no sense.

Although Merck relies upon *Burke*, *Kirby*, and *Wood*, it nowhere mentions those cases' consistent theme that inquiry notice is based on an investor's *ability* to discover the relevant facts – much less the similar points the Court made in *Foster* and *Sprague*. *See supra* pp. 30-32. Nor does Merck deal with the Court's repeated analysis in those cases of particular inquiries that fraud victims could and should have made and the results those inquiries would have achieved. *See supra* pp. 31-32. Similarly, Merck relies on *TRW* for the proposition that "a plaintiff could be on inquiry notice without possessing information specifically relating to each element . . . of the violation," Br. 21-22, but omits *TRW*'s much more telling statement that the plaintiff in that case would be "on

'inquiry notice' . . . *only* if a reasonable person in her position *would have learned* of [her] injury in the exercise of due diligence," 534 U.S. at 30 (emphases added).[18] Merck's patchwork of selective quotations undercuts its entire theory of the case.[19]

### B. Mere Suspicion Of Wrongdoing Does Not Commence The Limitations Period

**1.** Merck offers two alternative arguments linking the date on which plaintiff receives information merely suggestive of some kind of wrongdoing to the

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[18] Merck also leaves out *TRW*'s approving quotation of Professor Corman's statement that "'[i]t is obviously unreasonable to charge the plaintiff with failure to search for the missing element of the cause of action if such element would not have been revealed by such search,'" 534 U.S. at 30 (quoting 2 Corman §11.1.6, at 164), which is directly on point and contrary to Merck's position.

[19] Cases cited by Merck make the same point. *See Association of Commonwealth Claimants v. Moylan*, 517 N.W.2d 94, 102 (Neb. 1994) ("[D]iscovery occurs when the party knows of facts sufficient to put a person of ordinary intelligence and prudence on inquiry which, if pursued, *would lead to the discovery* of facts constituting the basis of the cause of action.") (emphasis added), *cited at* Br. 40; *Teall v. Slaven*, 40 F. 774, 778 (N.D. Cal. 1889) (quoting extensively from *Wood*), *cited at* Br. 44 n.12; *Andrews v. Dole*, 1 F. Cas. 878, 884 (D.N.J. 1875) ("[T]he postponement is not until the discovery of the fraud, but until the period of time when, with due diligence, he *might have discovered* it.") (emphasis added), *cited at* Br. 44 n.12; *Holman v. Hansen*, 773 P.2d 1200, 1203 (Mont. 1989) (inquiry notice means "notice or information of circumstances which would put [one] on inquiry which if followed *would lead to knowledge*") (internal quotations omitted; emphasis added), *cited at* Br. 40; *Blegen v. Monarch Life Ins. Co.*, 365 N.W.2d 356, 357 (Minn. Ct. App. 1985) ("[A] party must be deemed to have discovered the fraud when, in the exercise of proper diligence, he *could and ought to have discovered* it.") (internal quotations omitted; emphasis added), *cited at* Br. 25.

date that the limitations period for a §10(b) violation commences. *First,* Merck contends "the date on which the plaintiff was on inquiry notice" – defined as the receipt of suggestive information – should "always trigger the running of the limitations period." Br. 40. That contention cannot be squared with the statutory text. The words "discovery of the facts constituting the violation" do not mean "possess[ion] [of] a quantum of information sufficiently suggestive of wrongdoing that [one] should conduct a further inquiry." Br. 20.[20] By Congress's direction, the limitations period begins with the former, not the latter.[21]

Merck offers no case from this Court adopting the Draconian rule that information "suggestive of wrongdoing" puts a party immediately on constructive notice of all elements of its claim. Indeed, it is well-established that a plaintiff "must [have] more than mere suspicion" before being charged with "knowledge of fraud as a matter of *law*." 2 Corman §11.5.1, at 185. The case Merck touts as stating the "traditional[] operat[ion]" of inquiry notice, *Wood*, merely holds that, "'[w]hatever is notice enough to . . . call for inquiry, is notice of every thing to which such inquiry *might have led.*'" Br. 39-40 (quoting 101 U.S. at 141) (emphasis added). But Merck never identifies what facts investors here could have discovered through a reasonable inquiry in the period

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[20] Indeed, Merck itself concedes that its proposed standard is *not* the same as "discovery" – if inquiry notice does not attach before "[a] plaintiff . . . could . . . be said to have *discovered* his claim," then "the doctrine of inquiry notice would effectively do no work." Br. 23.

[21] Merck's rule also cannot be reconciled with Congress's inclusion of an express constructive-discovery provision in 1933 Act §13 and its omission of one from §1658(b)(1). *See supra* p. 25 (quoting 15 U.S.C. §77m).

from September to November 2001 that "might have led" them to the facts constituting a §10(b) violation. Merck therefore cannot prevail under *Wood*'s standard. *See infra* pp. 54-55.

*Second,* perhaps recognizing that its proposal lacks foundation in §1658(b)'s text, Merck offers an alternative formulation under which a "plaintiff should be entitled to an additional period of time before the limitations period commences only when he conducts a reasonably diligent investigation." Br. 43. That, as Merck concedes (at 46), is "functionally equivalent" to an ordinary equitable-tolling analysis, which is a judicially created rule based on the assumption that a court may equitably extend a statutory deadline in a small number of cases: it is "the exception, not the rule." *Rotella*, 528 U.S. at 561. In §1658(b)(1), Congress adopted the opposite approach. It crafted a limitations period starting with discovery of the facts constituting the violation as the rule, not the exception. Placing the burden on plaintiffs in every securities-fraud case to establish an entitlement to equitable tolling literally ignores §1658's text: doing so would create the same legal framework that would apply under an ordinary statute of limitations based on the date of the violation, subject to the usual doctrines of fraudulent concealment and equitable tolling. Congress meant to do something different with §1658(b)(1).

The cases cited by Merck applying nonstatutory equitable doctrines to differently worded statutes do not help it. *See* Br. 43 (citing *Holmberg v. Armbrecht*, 327 U.S. 392, 393-94 (1946); *United States v. Diamond Coal & Coke Co.*, 255 U.S. 323, 332 (1921); *Bailey*, 88 U.S. at 347). Without finding *any* lack of diligence by plaintiffs, those cases all merely stated

in general terms that a plaintiff must be diligent (or at least free of negligence or laches) to take advantage of the discovery rule as a matter of equity. *See Holmberg*, 327 U.S. at 397; *Diamond Coal*, 255 U.S. at 332; *Bailey*, 88 U.S. at 349-50. None held that a plaintiff's suit could be time-barred for lack of diligence without the court first determining that the plaintiff should have discovered the fraud earlier through reasonably available means.[22]

Merck also incorrectly relies on *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997). *Klehr* adopted for civil RICO claims the standard that applies when an antitrust claim has been fraudulently concealed: a plaintiff has not been diligent unless "'he neither knew nor, in the exercise of due diligence, could *reasonably have known* of the [defendant's] offense.'" *Id.* at 195 (quoting 2 Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶338, at 152 (rev. ed. 1995)) (emphasis added). Far from supporting Merck's punitive proposal, *Klehr* merely provides another example where the limitations period begins running no earlier than the date on which plaintiffs should have discovered the relevant facts.

Merck's policy arguments also ignore the substantial waste of resources that its theory would create when (as in this case) the facts constituting the viola-

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[22] *Diamond Coal* in particular undercuts Merck's argument. The district court there had refused the government the benefit of the discovery rule because of alleged laches in discovering the fraud. *See* 255 U.S. at 329-30, 332. This Court rejected that result, explaining that the finding of laches "depend[ed] upon the existence of *knowledge* of . . . *facts*" establishing the fraud or "of knowledge of other facts from which they were reasonably deducible." *Id.* at 334 (emphases added). *Diamond Coal* thus supports respondents' position that the appropriate focus of the discovery rule is what an investor knew or should have known.

tion are not discoverable. On Merck's theory, its investors should have spent time, money, and effort on inquiries – even though Merck continuously provided reassurances that such inquiries were unnecessary – despite the lack of available information. Congress could not have intended such a perverse result, which would be contrary to its policy against the filing of premature federal securities actions lacking a substantial factual basis. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313-14 (2007). To penalize investors in such circumstances (while adding an additional protection to defendants) conflicts with the balance struck by Congress in §1658 between a limitations period based on "discovery" and "repose" after five years.

**2.** The only cases supporting Merck's forfeiture approach are recent formulations from the Second and Third Circuits. But the Second Circuit has never provided any legal foundation for its "two-track" approach or explained its departure from the traditional discovery rule that it applied in *Armstrong v. McAlpin*, 699 F.2d 79, 88 (2d Cir. 1983) (which had appropriately cited, *inter alia*, *Wood* and *Higgins*). The Third Circuit recognized that it was not adopting the rule followed in other circuits, which based inquiry notice on what a reasonable inquiry, if conducted, would have found. *See Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239 (3d Cir. 2001). The Third Circuit also based its rule on policies applicable to RICO, not §10(b), *see id.* at 253 & n.16, and that analogy is inapt. *See supra* p. 39.

More importantly, Merck's rule cannot be squared with Congress's purpose in enacting §1658 in 2002. Congress sought to expand investor remedies and strengthen deterrence after the Enron and Worldcom

frauds. It is inconceivable that Congress intended to accomplish that result by deeming plaintiffs to have "discovered" facts that were unavailable due to a defendant's own fraud. Nor was Congress likely to anticipate that any court would interpret §1658(b) in such a manner in 2002: *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314 (3d Cir. 2002), the first securities case in which the Third Circuit applied the inquiry notice "rule" it adopted in *Mathews*, had not been decided, and the Second Circuit did not fully articulate its approach until 2003, *see LC Capital Partners, L.P. v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 155-56 (2d Cir. 2003).

### C. The Established Constructive-Discovery Standard Presents No Undue Difficulty

Merck argues that its proposed rule avoids "grave difficulties in application" because courts will not have to take into account "hypothetical inquiries about what a reasonably diligent investigation would have entailed." Br. 20, 50. That contention flies headlong into more than a century of precedent. *See, e.g., TRW*, 534 U.S. at 30 (stating that the question is what "a reasonable person . . . would have learned"); *Kirby*, 120 U.S. at 138 (asking when, "with reasonable diligence, [the fraud] might have been discovered"); *Sprague,* 103 U.S. at 762 (explaining that a party "can only be charged with knowledge of the facts which she might have learned by inquiry"); *see also supra* pp. 30-32.

More broadly, a fundamental precept of the common law presumes that "the perspective of the hypothetical 'reasonable person' gives content to concepts such as 'negligent' behavior." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997). This Court has applied that principle in constructive-

discovery cases without hesitation. *See, e.g., Foster*, 146 U.S. at 100 (examining inquiries that plaintiff could have made before concluding that "[t]he slightest effort on his part would have apprised him" of the relevant facts); *Wood*, 101 U.S. at 140 (listing inquiries that plaintiff might have made before concluding that "proper diligence could not have failed to find a clew in every case that would have led to evidence not to be resisted"). As Professor Dawson explained, use of a hypothetical inquiry "introduces new variables into the arithmetic of the limitation acts, but it seems imperatively required by their larger social purpose and it is functionally related to the equitable doctrine of 'laches' from which these exceptions are historically derived." Dawson, 31 Mich. L. Rev. at 619-20.

Merck's complaint (at 50) that this longstanding analysis (which is only a variant of the general common-law negligence standard) creates "difficulties" is therefore unpersuasive.[23] When applied to this case, that analysis leads inexorably to the conclusion that a reasonable investor would not have discovered Merck's misrepresentations of belief concerning the naproxen hypothesis before November 6, 2001. Therefore, no constructive discovery (based on inquiry notice, or otherwise) triggered the limitations period to bar respondents' complaint.

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[23] Merck's proposed rule, moreover, does not seem likely to avoid hypothetical inquiries, as Merck presumably would reserve defendants' ability to challenge the "reasonableness" of any inquiries actually undertaken by or on behalf of an inquiring plaintiff by comparing them to what more a hypothetical reasonable investor would have done.

### D. The "Facts Constituting [A] Violation" Under §1658(b) Include Scienter

Merck also would have this Court declare as a matter of law that any misstatement of fact made in the securities context – even without any indication that it was made with an intent to deceive – triggers inquiry notice of fraud. Br. 22-23. There is no basis to interpret §1658(b) to exclude scienter when the violation referenced in §1658(b) encompasses "fraud, deceit, manipulation, or contrivance," all of which inherently connote scienter. *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164 (1994); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 197 (1976). *See supra* pp. 21-25.

Merck incorrectly (and without citing the decision below) characterizes the Third Circuit as adopting a "bright-line rule that a plaintiff who possesses information that the defendant made a misstatement can *never* be on inquiry notice until he also possesses discrete information specifically relating to scienter." Br. 22. That mischaracterizes the opinion of the Third Circuit, which decided this case (as can this Court) solely on the ground that the *falsity* of Merck's statements could not have been known until, at the earliest, October 2003. Pet. App. 47a. Thus, this Court should decline Merck's invitation (at 39) to reverse a rule that the Third Circuit did not adopt below.

If the Court reaches the question, however, it should hold that, because scienter is an element of a §10(b) violation, actual or constructive knowledge of scienter is essential to trigger the running of the statute. *See supra* pp. 25-27. Merck's argument (at 22) that evidence of scienter "is usually proved through inferences from circumstantial evidence"

misses the point. That scienter can be inferred from sufficient circumstantial evidence does not compel the conclusion that Congress intended the statute to eliminate the need for any such inference before the two-year limitations period begins. In some cases, where the circumstances surrounding a misstatement *do* suggest scienter, those circumstances will furnish the necessary information. But in circumstances, as here, that do not indicate a defendant's intent to deceive, an investor cannot be penalized for failing to intuit scienter.

Merck contends that, under *United States v. Kubrick*, 444 U.S. 111 (1979), *Klehr*, and *Rotella*, investors need not have suspicion of fraud before they have a duty of inquiry. Br. 25-27. However, none of these cases involved statutes with an explicit discovery rule, let alone one that embraced the elements of the violation. *See supra* p. 39 (discussing *Klehr*); *Kubrick*, 444 U.S. at 113 n.1 (quoting 28 U.S.C. §2401(b)). *Rotella* involved whether the RICO statute of limitations, which is triggered by a plaintiff's "injury," would be tolled pending discovery of a "pattern" of racketeering. The Court concluded there that fraud "is generally associated with a different accrual rule." 528 U.S. at 557. In *TRW*, the Court suggested that a plaintiff who discovers she was improperly denied credit would have a reason to suspect *negligence*, not necessarily *willfulness*. *See* 534 U.S. at 29-30. It is far more reasonable to suspect *negligence* from an error than to adopt a blanket rule that all errors raise a suspicion of fraud.

Indeed, Merck's proposed rule generally is inconsistent with the concept of discovery, which only requires parties to behave with "ordinary care and attention," *Wood*, 101 U.S. at 141 (internal quota-

tions omitted), and does not require investors to see fraud in every shadow.

### E. Congress Never "Ratified" Merck's Version Of Inquiry Notice

Merck claims (at 20) that, in enacting §1658(b), Congress "ratified [the] understanding" that "the Section 9(e) limitations provision, as applied to Section 10(b) actions, incorporated . . . the principle of inquiry notice." Merck's reliance on *Berry v. Valence Technology, Inc.*, 175 F.3d 699 (9th Cir. 1999), however, is misplaced. That case expressly *declined* to "decide whether actual discovery or inquiry notice applies" to Rule 10b-5 actions and criticized other appellate court decisions as "contrary to the specific guidance issued by the Court" in *Lampf*. *Id.* at 704 (internal quotations omitted); *see also id.* at 703.

Even if the lower courts uniformly had agreed that §9(e) incorporated a concept akin to "inquiry notice" before Congress enacted §1658(b), they did not agree *when* inquiry notice should be triggered and what consequences flow from a plaintiff's failure to investigate. As Merck itself concedes (at 39), "courts of appeals have taken conflicting positions as to when the limitations period begins running."[24] Given that

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[24] *See Berry*, 175 F.3d at 704 (noting disagreement among appellate courts and opinion that the statute of limitations begins to run only once the investor "should have discovered the facts underlying the alleged fraud") (internal quotations omitted); *see also Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1201 (10th Cir. 1998) ("limitations period begins to run" not with an investor's "duty to exercise reasonable diligence," but when "the investor, in the exercise of reasonable diligence, should have discovered the facts underlying the alleged fraud"); *Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 129 F.3d 222, 225 (1st Cir. 1997) (refusing to decide whether statute of limitations ran from date investors had a duty to inquire about

lack of clarity, "[i]t would thus be impossible to say which view Congress might have endorsed." *United States v. Wells*, 519 U.S. 482, 496 (1997).[25]

The sole piece of legislative history relating to inquiry notice cited by Merck (at 20) is a statement of senators who voted *against* §1658(b). But "[t]he fears and doubts of the opposition are no authoritative guide to the construction of legislation." *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 394 (1951). That background, therefore, offers no support for Merck's strained reading of the statute's plain text.

## III. THE COMPLAINT WAS TIMELY FILED

The Third Circuit correctly held that Merck cannot establish, as a matter of law, that respondents had a reasonable basis to believe (or, indeed, even to suspect) that Merck had made a material misrepresentation in violation of §10(b) more than two years before the first securities complaint was filed.

### A. Respondents Were Not On Inquiry Notice Prior To November 2001

#### *1. Nothing suggested that Merck's statements of opinion were false before November 2001*

As the Third Circuit recognized, *see* Pet. App. 33a-34a, and as Merck now concedes, Br. 38, the gravamen of respondents' claims is that Merck falsely represented that it believed that the naproxen

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fraud or on the later date when an investor could have discovered fraud).

[25] Merck's argument suffers even further because Congress nowhere discussed the case law, thereby making this Court's interpretive task "'treacherous.'" *NLRB v. Plasterers' Local Union No. 79*, 404 U.S. 116, 129-30 (1971) (quoting *Girouard v. United States*, 328 U.S. 61, 69 (1946)).

hypothesis was the most likely explanation for VIGOR's results, when internally it actually had concluded the opposite.

As noted above, statements of belief "are factual in two senses: as statements that the [speaker] . . . hold[s] the belief stated and as statements about the subject matter of the reason or belief expressed." *Virginia Bankshares*, 501 U.S. at 1092. Investors had no basis even to suspect before November 6, 2001, that Merck did not believe its hypothesis, or that the hypothesis lacked a reasonable basis. Respondents therefore could not have been on any kind of notice (even under Merck's erroneous standard) that Merck's statements were *false*, let alone that they had violated §10(b).

In 2000 and 2001, Merck investors and the financial community were well aware that VIGOR's results *could* be attributable to a harmful effect of Vioxx rather than to a beneficial effect of naproxen. *See supra* pp. 5-8. Merck's investors were charged with that knowledge. Merck's statements promoting the naproxen hypothesis did not (and were not meant to) lead investors to believe there was *no* possibility Vioxx was harmful. Rather, those statements were meant to (and did) induce investors to believe that Merck, with its particular expertise and intimate knowledge, believed that the most "likely" explanation was that Vioxx was not harmful. Because "[p]robabilities determine the value of stock," *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992), Merck's opinion was of critical importance. *See Virginia Bankshares*, 501 U.S. at 1091 ("[s]hareholders know that [corporate officers] usually have knowledge and expertness far exceeding the normal investor's resources").

Merck contends that investors had reason to suspect fraud because of publicly available information that "debat[ed] the merits of (and, in many instances, cast[] doubt on) Merck's position that the 'likely' explanation for the disparity in cardiovascular events was that naproxen prevented blood clots." Br. 34. But those debates suggested only that Merck's interpretation of medical data was inconclusive, *i.e.*, that Merck might have been mistaken in its belief in the naproxen hypothesis. More was needed to provide reasonable grounds even to suggest that Merck's stated belief in its naproxen hypothesis was not made in good faith, *i.e.*, was *false*.

The very sources that Merck claims should have created a duty of inquiry expressly accepted the naproxen hypothesis as plausible, suggesting that Merck had a reasonable basis for supporting it.[26] Investors also had no reason to doubt the veracity of Merck's contemporaneous representations that it had additional "very, very reassuring" undisclosed data showing that "VIOXX does not result in any increase

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[26] *See* JA326 (*JAMA* article: VIGOR data "can be explained by either a significant prothrombotic effect from [Vioxx] or an antithrombotic effect from naproxen (or conceivably both)"); JA340 (DDMAC letter: describing the naproxen hypothesis as "a possible explanation" of VIGOR's results); JA504-06 (Oct. 9, 2001 *NYT* article: reciting Merck's unchallenged representation that it had "found no evidence that Vioxx increased the risk of heart attacks" in trials using different comparator drugs or placebo; and presenting issue as one where the available data are insufficient to "fully resolve[]" a scientific debate). Other articles Merck cites also contained unchallenged representations from Merck that its clinical data (outside of VIGOR) showed no disparity in cardiovascular events between Vioxx and non-naproxen NSAIDs or placebo, JA361, 367, 371, or quoted market analysts endorsing the naproxen hypothesis, JA367-68, 370-71.

in cardiovascular events compared to placebo." JA119 (¶214) (responding to *JAMA*'s article).[27] Such reassurances represent "words of comfort" that allay investors' suspicions and can be found to extinguish any "notice" of fraud they might otherwise have had. *Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 194 (2d Cir. 2003) (internal quotations omitted).

In addition, FDA itself confirmed the apparent reasonableness of the naproxen hypothesis on numerous occasions, *e.g.*, in February 2001 (when leading members of an FDA advisory committee stated that the naproxen hypothesis appeared to be the best explanation for VIGOR's results); in DDMAC's September 2001 letter; and in April 2002 when FDA expanded Vioxx's approved uses. JA145 (¶256). A reasonable investor giving "ordinary care and attention" to his investment, *Wood*, 101 U.S. at 141 (internal quotations omitted), was not required to inquire further into whether Merck's own primary regulator was incorrect about the reasonableness of the naproxen hypothesis.

*2. Violations of FDA regulations did not suggest a material misstatement of opinion*

In its September 2001 letter to Merck, DDMAC charged that certain marketing statements made by a Merck consultant and Merck personnel manning a convention sales booth to approximately 100 doctors and 1,300 pharmacists failed to disclose (i) that Merck's naproxen hypothesis was unproven; and (ii) that another reasonable explanation for VIGOR's results was that Vioxx caused adverse cardiovascular

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[27] *See also* JA95-96 (¶166) (Merck assuring investors that non-public data showed "no difference in the incidence of cardiovascular events . . . among patients taking Vioxx, other NSAIDs and placebo").

events. JA339, 342-46, 351-52. Consistent with the FDA committee's previous position in February 2001, and the agency's later approval of expanded uses in April 2002, DDMAC's letter did *not* contend that the naproxen hypothesis was incorrect. Instead, it *confirmed* that the naproxen hypothesis was a "possible" and "reasonable" explanation for VIGOR's results and that "the reason for the difference between Vioxx and naproxen has not been determined" and was "not clear." JA340, 342, 344. The only remedy it ordered was a letter of correction to those doctors and pharmacists who had heard the particular presentations. JA353.

Nothing in DDMAC's letter would have led a reasonable investor to believe that the naproxen hypothesis was even incorrect, much less suspect that Merck itself *internally* had rejected the hypothesis as the "likely explanation" years earlier.[28] Rather, that investor would have concluded (as financial market participants did) that the naproxen hypothesis was still unproven but viable and that Merck merely had been overzealous in running afoul of FDA's strict marketing regulations.[29]

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[28] Merck asserts that, "[t]o the extent that FDA accused Merck of 'misrepresent[ing] the safety profile for Vioxx,' it would at a minimum suggest the possibility that any opinion expressed by Merck concerning Vioxx's safety profile was not sincerely held." Br. 36-37 n.8. To the contrary, the omission of publicly available alternative scientific explanations for the VIGOR data from the specific marketing presentations made to 100 doctors and 1,300 pharmacists suggests overzealous marketing by a handful of individuals, not a fraud on financial markets.

[29] The point is not, as Merck says, simply that DDMAC's letter "did not specifically accuse Merck of securities fraud." Br. 35 (emphasis omitted). Rather, DDMAC stated affirma-

In addition, because the market had known already for some time that Vioxx might increase the risk of heart attacks, and that the naproxen hypothesis was an unproven theory, DDMAC's letter gave Merck's investors no reason to suspect that Merck had withheld any material information from investors.[30] In an "efficient market," securities analysts, professional investment advisors, and other market professionals evaluate "all publicly available information" about a company. *Basic*, 485 U.S. at 246, 248. By their propagation of that information and their trading patterns, they cause the company's stock price to reflect the totality of that information. *See id.* at 246. It is well-established that a failure to repeat information that is already "well known to the market" is immaterial as a matter of law. *E.g.*, *Longman v. Food Lion, Inc.*, 197 F.3d 675, 684 (4th Cir. 1999); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1115 (9th Cir. 1989) ("[I]n a fraud on the market case, the defendant's failure to disclose material information may be excused where that information has been made credibly available to the market by other sources."); *accord Basic*, 485 U.S. at 248. Even outside the efficient-market context, the securities laws do not require repetitive disclosure of publicly known information. *See, e.g.*, *Klein v. General Nutrition Cos.*, 186 F.3d 338, 342-43 (3d Cir. 1999).

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tively that the naproxen hypothesis was a possible explanation, though not proven, and that the naproxen hypothesis had a "reasonable" basis. JA340.

[30] That DDMAC's letter contained nothing new to the market is shown by several facts: (1) numerous analysts said so, (2) no analyst downgraded Merck's stock after the letter, and (3) Merck's stock suffered no long-term price drop. *See supra* p. 8.

Those principles contrast sharply with FDA marketing rules. FDA's regulations seek to ensure that each consumer and health care professional *actually receives* full and balanced information concerning a drug's risks. Thus, FDA requires that each promotional item or advertisement, viewed in isolation, presents a "fair balance" of information relating to both effectiveness and risks, even where that information has previously been widely disseminated. *See* 21 C.F.R. §202.1(e)(5)(ii). Communications to patients or health professionals that violate those regulations may thus be deemed "false, lacking in fair balance, or otherwise misleading" within the particularized meaning of FDA's regulations, JA339, but that does not make them Rule 10b-5 violations or even suggestive of a §10(b) violation.

In DDMAC's letter, FDA regulations required that information regarding Vioxx's risks be included in each marketing statement, even though, as an analyst noted, those risks were "likely . . . already common knowledge in the medical community," JA618. For the investment community, which also long had known that the naproxen hypothesis was only a hypothesis and that there was a risk that Vioxx might cause heart attacks, nothing in DDMAC's letter suggested that Merck had withheld any material information from the public.

*3. Consumer lawsuits*

The handful of tort suits filed by Vioxx users in 2001 who claimed that the drug had injured them did not give Merck's investors a reason to suspect a §10(b) violation. Personal injury lawsuits against a drug manufacturer by users of the drug are unremarkable. Further, because those suits were based solely on VIGOR's results, *JAMA*'s article, and

DDMAC's letter, they offered investors no more information than those sources originally had, and the elements for the claims in those consumer and tort actions bore no similarity to those needed to suggest a §10(b) violation. *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).

*4. The Harvard Study*

As the Third Circuit correctly found, Pet. App. 47a, reporting of the Harvard Study was the earliest possible time at which investors had a reason to question whether Merck had a genuine, reasonable belief in its naproxen hypothesis. That large, independent, publicly available study cast considerable doubt on Merck's repeated assurances that Vioxx was not pro-thrombotic. Merck's immediate and aggressive criticism of the study's design raised questions about Merck's candor in the Vioxx debate. But reasonable investors also might well have continued to rely without negligence on Merck's continuing reassurances that its own internal analyses and studies showed "no statistically significant difference in the risk of heart attacks" between Vioxx and non-Vioxx users. JA166 (¶293).[31]

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[31] Though Merck makes much (Br. 48) of the fact that one of respondents' counsel said his client had not conducted an "investigation," JA994, that statement should not be taken to mean that respondents never considered public information regarding their investments. Where market professionals did not report evidence suggestive of securities fraud at a publicly traded company, it is unreasonable to require more inquiry by a reasonable investor.

### B. Respondents Had No Means To Discover The Facts Constituting Merck's Violation

Even if, as Merck contends, respondents had a duty of inquiry prior to November 2001, Merck has failed to establish that "the means of discovery [was] in [respondents'] power." *Wood*, 101 U.S. at 141. For that reason, there was no actual or constructive discovery, and the statute of limitations could not have run.

Merck has never identified any facts available to investors that would have revealed the violation alleged before November 6, 2001. No information accessible to an ordinary investor who inquired at that time demonstrated that the naproxen hypothesis was likely wrong, much less that Merck did not actually believe in it. The means of discovery did not reside in documents to which respondents had access, *see Burke*, 83 U.S. at 401, nor were they available from public records, *see Wood*, 101 U.S. at 139-40. Instead, the facts constituting the violation could be pieced together only from internal data and emails "in the control of the putative defendant, unavailable to the plaintiff." *Kubrick*, 444 U.S. at 122.

In arguing that its investors had a reason to suspect fraud, Merck relies on what it calls "an enormous volume of news stories, academic articles, and analyst reports debating the merits of (and, in many instances, casting doubt on) Merck's position" supporting the naproxen hypothesis.[32] Br. 34. But expressions of "doubt" about an opinion's substantive

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[32] The stories, articles, and reports also were available, of course, to the market – which as a whole did not discover Merck's fraud until much later. JA198 (¶337) (analyst's comment in November 2004 that the newly disclosed emails showed "the situation might not be as innocent as we thought").

correctness do not suggest fraud, much less enable a reasonable investor to discover Merck's violation of §10(b). In addition, even FDA – with its scientific expertise and access to (some of) Merck's confidential data – accepted the legitimacy of the naproxen hypothesis and, at least as of April 2002, considered the "significance" of VIGOR's results to be "unknown." JA140 (¶251). And doctors continued to write billions of dollars' worth of Vioxx prescriptions. With the true facts tightly under its corporate control, Merck cannot carry its burden to establish, as a matter of law, that investors should have discovered facts constituting a violation prior to November 2001.[33]

* * *

The Third Circuit thus correctly held that, as of two years prior to the first complaint's filing, "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. . . . [I]n 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.'" Pet. App. 46a (first and second alteration added). Respondents therefore were not on inquiry notice that Merck's statements of belief were false, and thus they could

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[33] Additionally, Merck continued to make independently actionable false statements after November 2001. Each new false statement constituted a new "untrue statement of a material fact or . . . omi[ssion] [of] . . . a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b). Because this action was filed within two years of those statements, the statute cannot have run with respect to those violations.

not have had a duty to inquire as to the existence of §10(b) violations.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

MAX W. BERGER
WILLIAM C. FREDERICKS
ELLIOTT J. WEISS
BRUCE D. BERNSTEIN
ANN M. LIPTON
BOAZ A. WEINSTEIN
ADAM H. WIERZBOWSKI
BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 554-1400

DAVID A.P. BROWER
JESSICA J. SLEATER
BROWER PIVEN
A Professional Corporation
488 Madison Avenue
New York, New York 10022
(212) 501-9000

MATTHEW GLUCK
RICHARD H. WEISS
MATTHEW A. KUPILLAS
ROLAND W. RIGGS
MILBERG LLP
One Pennsylvania Plaza
New York, New York 10119
(212) 594-5300

DAVID C. FREDERICK
*Counsel of Record*
GREGORY G. RAPAWY
MICHAEL E. JOFFRE
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900

JULES BRODY
MARK LEVINE
STULL, STULL & BRODY
6 East 45th Street, 5th Floor
New York, New York 10017
(212) 687-7230

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