
IN THE
Supreme Court of the United States

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

v.

RICHARD REYNOLDS, ET AL.,
Respondents.

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

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Did the Third Circuit err in holding – in accordance with the law of every circuit – that a plaintiff is not on inquiry notice of securities fraud until it receives “storm warnings” of that fraud and in determining that, under the particular facts of this case, no storm warnings existed?

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INTRODUCTION

The Third Circuit correctly held, based on a detailed factual analysis of Respondents'¹ Complaint,² that the statute of limitations had not expired when Respondents filed this securities fraud lawsuit.³ In so doing, the Third Circuit applied a test that has been endorsed by every Court of Appeals to consider the issue. The circuits uniformly hold that a plaintiff is not on "inquiry notice" until there are sufficient facts available to the plaintiff – "storm warnings" – that would arouse suspicions of the alleged fraud in a reasonable investor. Only after concluding that this first prong of the statute of limitations test is satisfied – *i.e.*, sufficiently suspicious facts exist to trigger a duty to investigate – do courts consider the second prong, namely, whether the plaintiff conducted a reasonable investigation and whether such investigation would have uncovered enough information to bring suit. This case involves only the uncontroverted first prong of this analysis: the "storm warnings" prong.

The Third Circuit concluded that no storm warnings of the alleged fraud existed more than two years prior to the filing of the original complaint. The court's holding did not articulate a new or different standard for determining the existence of storm warnings. Rather, the decision resulted from a fact-bound analysis of the securities fraud alleged in

¹ Respondents include Co-Lead Plaintiffs in the securities fraud action currently before the District Court.

² Corrected Consolidated and Fourth Amended Class Action Complaint (filed June 14, 2005) ("Compl.").

³ The Complaint also asserts non-fraud claims under §§ 11, 12(a)(2), and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77l(a)(2), 77o.

Respondents' Complaint and whether publicly available information would have aroused suspicion of that fraud. As the Third Circuit recognized, the gravamen of the Complaint was that Petitioners believed that Merck's drug VIOXX ("Vioxx") was to blame for the results of a large-scale clinical trial – which showed that significantly more patients taking Vioxx suffered adverse cardiovascular events, particularly heart attacks, than patients who took the comparator drug, naproxen – but misled investors by proffering an opinion that these results were likely attributable to an alleged cardio-protective effect of naproxen rather than a harmful effect of Vioxx (the so-called "naproxen hypothesis"). The Third Circuit recognized that, as of November 6, 2001 (two years before the filing of the initial complaint), there were no storm warnings that Petitioners did not believe their naproxen hypothesis.

Because the court found no storm warnings, it had no need to (and did not) address the second prong of the statute of limitations test: whether, once Respondents received storm warnings, a reasonably diligent investigation would have yielded sufficient details of the fraud to file a complaint. As Petitioners themselves recognize, the purported circuit split they identify relates to that *second* prong of the test – *i.e.*, whether and when, *after* the plaintiff is under a duty to investigate, the statute of limitations is triggered. *See* Pet. 3. To the extent any such differences among the circuits on the second prong of the test produce different outcomes, those decisions have no application here. Absent storm warnings, Respondents had no duty to investigate in the first place. Petitioners may disagree with the Third Circuit's fact-bound conclusion that there were no storm

warnings that Petitioners did not actually believe their publicly proffered naproxen hypothesis, but they cannot trace their disagreement to the Third Circuit's articulation of the first prong of the test, which is consistent with that of every other circuit.

Thus, this case does not implicate any circuit split or warrant further review. The disagreement between the District Court and the Third Circuit turned not on the applicable law but on how, as a factual matter, to characterize Respondents' claims. The District Court, prompted by Petitioners, mistakenly characterized Respondents' claims as alleging that Merck misrepresented the "fact" that the naproxen hypothesis was unproven.⁴ Proceeding from this fundamental misunderstanding of Respondents' allegations, the District Court held that there were storm warnings that the naproxen hypothesis was unproven. The Third Circuit correctly recognized that the Complaint did not allege such a fraud; rather, the Complaint alleged that Petitioners misled investors by proffering an opinion on medical research results that they did not honestly hold. Such highly fact-bound questions concerning the nature of the fraud alleged and whether storm warnings of that fraud existed do not warrant this Court's review.

⁴ Petitioners' argument to this Court is premised on the same mischaracterization of the gravamen of Respondents' claims.

STATEMENT

A. Statutory and Doctrinal Background.

Section 10(b) of the Securities Exchange Act of 1934 (“1934 Act”) provides that “[i]t shall be unlawful for any person ... [t]o use or employ, in connection with the purchase or sale of any security ... , any manipulative or deceptive device or contrivance.” 15 U.S.C. § 78j(b). A private right of action “ha[s] been implied under th[is] statute for nearly half a century.” *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350, 358 (1991). While most securities fraud claims are predicated on factual misstatements, “statements of reasons, opinion, or belief” may also form the basis of a claim, if the speaker “did not hold the beliefs or opinions expressed.” *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1090 (1991); *see id.* at 1090-96.

In *Lampf*, this Court held that a one-year statute of limitations governed the private right of action under § 10(b), requiring plaintiffs to bring claims “within one year after the discovery of the facts constituting the violation.” 501 U.S. at 359-60, 364 (based on limitations period for similar 1934 Act causes of action). Subsequently, Congress codified a two-year statute of limitations for private securities fraud claims. 28 U.S.C. § 1658(b) (“a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement ... may be brought not later than the earlier of ... 2 years after the discovery of the facts constituting the violation”).

The circuits agree that the statute of limitations is triggered when the plaintiff has either actually or constructively discovered the “facts constituting the

violation.” The circuits also agree that the appropriate question for determining whether a plaintiff is on inquiry notice is to ask whether the plaintiff received sufficient “storm warnings” of the alleged fraud such that a reasonable investor would have investigated further. All circuits agree that, if a plaintiff received no such “storm warnings,” the statute of limitations does not begin to run. *See* pp. 14-16, *infra*.

B. Nature of the Action.

1. Respondents’ Complaint.

On November 6, 2003, the initial securities fraud class action complaint was filed. On February 23, 2005, the Judicial Panel on Multidistrict Litigation transferred the various Vioxx-related securities actions to the District Court in New Jersey, where they were consolidated. On June 14, 2005, Respondents filed the Complaint at issue on this appeal.

The gravamen of Respondents’ Complaint was that Merck and its senior officers – Petitioners here – made false statements of opinion by asserting that they believed that the results of the large-scale Vioxx Gastrointestinal Outcomes Research clinical trial (“VIGOR”) were attributable to alleged cardioprotective properties of naproxen, when in fact they believed that these results were attributable to Vioxx’s harmful cardiovascular effects. *See* Pet. App. 35a. As the Complaint alleged:

In May 1999, the Food and Drug Administration (“FDA”) approved Vioxx, a new drug developed by Merck. Vioxx is a nonsteroidal anti-inflammatory drug (“NSAID”) used in the treatment of pain from arthritis and other ailments. Traditional NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: one which helps maintain

the stomach's protective lining and one which is associated with pain and inflammation. In contrast, Vioxx suppresses only the latter enzyme, and therefore was believed to significantly reduce the harmful gastrointestinal side effects associated with long-term use of other NSAIDs. *See id.* at 5a.

Merck vigorously touted Vioxx as possessing the pain-suppressing benefits of traditional NSAIDs, but without the harmful gastrointestinal side effects. The market, in turn, viewed Vioxx as a potential “blockbuster” and “savior” for Merck. *See id.*

Well before introducing Vioxx to the market, however, Merck had serious concerns that Vioxx caused harmful cardiovascular events, including heart attacks. In internal emails from 1997, which were not publicly disclosed until November 2004, top Merck scientists stated that the “possibility of increased [cardiovascular] events is of great concern” (Compl. ¶ 88) and could “kill [the] drug” (Pet. App. 6a) (alteration in original).

In January 1999, Merck commenced the VIGOR trial, which compared Vioxx to naproxen, the active ingredient in brand-name pain relievers such as Aleve. The purpose of VIGOR was to demonstrate that Vioxx caused fewer gastrointestinal problems than traditional NSAIDs and to thereby allow Merck to seek a more favorable drug label for Vioxx from the FDA. VIGOR produced mixed results for Merck: Vioxx users suffered significantly fewer gastrointestinal problems than naproxen users but significantly more adverse cardiovascular events, particularly heart attacks. *See id.*

Reviewing those data, Merck internally concluded that Vioxx caused the higher rates of adverse cardio-

vascular events suffered by Vioxx users. Indeed, in a March 9, 2000 internal email, a senior Merck officer who was also the Company's top scientist responsible for the development of Vioxx wrote that the cardiovascular events among Vioxx users in the VIGOR trial "are clearly there" and that "it is mechanism based as we worried it was." Compl. ¶ 136; see Pet. App. 6a.

Despite having internally reached this conclusion, when Merck announced the VIGOR results to the market, it opined that the difference in rates of adverse cardiovascular events was likely the result of alleged cardio-protective properties of naproxen rather than a harmful effect of Vioxx (the "naproxen hypothesis"). For example, as Merck stated on March 27, 2000:

[S]ignificantly fewer [cardiovascular] events were observed in patients taking naproxen in this [gastrointestinal] outcomes study, *which is consistent with naproxen's ability to block platelet aggregation*. This effect on these events had not been observed previously in any clinical studies for naproxen. *Vioxx ... does not block platelet aggregation and therefore would not be expected to have similar effects*.

Id. at 7a (emphases added).

The VIGOR results were widely reported in the press, medical journals, and securities analyst reports. Market analysts, scientists, and the press immediately understood that there were two possible explanations for the VIGOR results: either Vioxx caused heart attacks or naproxen prevented them. Although Merck acknowledged that its naproxen hy-

pothesis was unproven and that no large-scale clinical trials had tested whether naproxen was cardio-protective, virtually all in the scientific and financial communities accepted Merck's naproxen hypothesis as the most likely explanation for the higher incidence of adverse cardiovascular events observed among Vioxx users in VIGOR. *See id.* at 8a.

Petitioners repeatedly assured the market of their belief in the naproxen hypothesis and that Vioxx was "safe." *See id.* at 45a-46a. Petitioners also projected that Vioxx, Merck's second-best selling drug, would continue to generate "blockbuster" revenues for the company. *See id.* at 5a. Many securities analysts echoed this sentiment and gave Merck their highest "buy" rating. *See id.* at 14a. Thus, the Complaint alleges that Merck's stock price remained higher than it would have been had the market known the truth: that Petitioners *actually* believed that Vioxx caused heart attacks.

On October 30, 2003, *The Wall Street Journal* reported that a large-scale study by Brigham and Women's Hospital found that Vioxx users had increased heart attack risk compared to patients taking Celebrex (a competitor drug that, like Vioxx, suppressed only the enzyme associated with pain and inflammation). *See id.* at 18a. Despite having sponsored this study, Merck criticized its findings.

On September 30, 2004, Merck withdrew Vioxx from the market after another study showed "an increased risk of confirmed [cardiovascular] events [in Vioxx users] beginning after 18 months of continuous therapy." Compl. ¶ 321. The falsity of Petitioners' statements regarding their own opinions, however, was not fully revealed until November 1, 2004, when

The Wall Street Journal published excerpts from internal Merck emails demonstrating that Merck had internally concluded years earlier that Vioxx caused adverse cardiovascular events. *See* Pet. App. 19a.

2. The District Court's ruling.

The District Court dismissed on a Rule 12(b)(6) motion all of Respondents' federal securities fraud claims as time-barred based on its characterization of the Complaint, holding that Respondents were on inquiry notice of Petitioners' fraud more than two years before filing the Complaint.

In determining when the statute of limitations began to run on Respondents' claims, the District Court conducted the two-step analysis used by all Courts of Appeals. The first step of that analysis asks whether there were "storm warnings" of the fraud sufficient to cause a reasonable investor to investigate the matter further. If such storm warnings exist, the inquiry proceeds to whether the plaintiff "exercised reasonable due diligence and yet w[as] unable to discover [its] injuries." *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (internal quotation marks omitted). In the Third Circuit, a plaintiff who fails to conduct an investigation in response to storm warnings is automatically deemed to fail the second prong of the test, regardless of whether further inquiry would have revealed the wrongful conduct. *See id.* at 401.⁵

In performing this analysis, the District Court, prompted by Petitioners, misapprehended the nature

⁵ Although the Third Circuit had no occasion to reach the issue, Respondents reserve the right to argue that, in the event *certiorari* is granted, a more lenient standard should govern when the second prong is triggered.

of Respondents' claims. The District Court did not address when Respondents were on notice that Petitioners did not actually believe in their naproxen hypothesis. Rather, the District Court considered the different question of when Respondents were on notice that the naproxen hypothesis was unproven or that Vioxx *might* increase the risk of heart attacks. Pet. App. 85a. In other words, the District Court characterized Respondents as alleging that Petitioners failed to disclose that the naproxen hypothesis was a theory rather than a proven fact, when Respondents had made no such argument and Respondents' claims were actually based on Petitioners' lack of good-faith belief in their stated "opinion" that the higher incidence of adverse cardiovascular events among Vioxx users in VIGOR was likely due to a cardio-protective effect of naproxen rather than a harmful effect of Vioxx. Because of this fundamental mischaracterization, the District Court concluded that Respondents were on inquiry notice of their claims no later than October 9, 2001, when a *New York Times* ("NYT") article reported both (a) that Merck continued to believe that the naproxen hypothesis was the most likely explanation for the VIGOR results, and (b) that – as had been previously reported since March 2000 – the naproxen hypothesis was unproven and Vioxx might cause heart attacks. *Id.* The District Court also relied on an earlier September 2001 warning letter from the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC"), admonishing Merck for failing to better inform physicians that the naproxen hypothesis was only a theory. *Id.* at 85a-86a. The District Court did not address if or when there were storm warnings that Petitioners misrepresented their own opinion about the naproxen hypothesis.

Because Respondents did not allege that they conducted their own investigation into Petitioners' conduct following the October 9, 2001 *NYT* article, the District Court held that the statute of limitations began to run from that date. *Id.* at 94a, 98a.

3. The Third Circuit's decision.

The Third Circuit reversed the District Court, finding that it had improperly characterized Respondents' claims and that, for the fraud actually alleged, there were no storm warnings before November 6, 2001 – and that Respondents accordingly were not on inquiry notice before that date.

The Third Circuit did not construe the Complaint as alleging that Petitioners misrepresented the fact that the VIGOR trial could support two possible explanations – something that had been clear since March 2000 when Merck first announced the VIGOR results. Instead, the court understood the Complaint to assert that Petitioners' statements of their belief in the naproxen hypothesis were not made in good faith – *i.e.*, that Petitioners “did not hold the belief or opinions expressed.” *Virginia Bankshares*, 501 U.S. at 1090-96. The Third Circuit found that, as of November 6, 2001, a reasonable investor would have had no reason to suspect that Petitioners' stated opinions about the validity of the “naproxen hypothesis” were false. *See* Pet. App. 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.”).

Under the Third Circuit's characterization of Respondents' Complaint, the public documents that the District Court believed had provided inquiry

notice were inapposite. As the Third Circuit explained, “Merck had long acknowledged and ... the market had incorporated” the fact that the naproxen hypothesis was an unproven explanation of the VIGOR results (and that the other explanation was that Vioxx caused heart attacks). *Id.* at 43a. Thus, when the DDMAC directed Merck to communicate better to doctors that the naproxen hypothesis was unproven and that Vioxx might cause serious cardiovascular harm, the DDMAC was simply requiring Merck, in the interests of patient safety, to publicize better those facts that had been disclosed previously, and repeatedly, to investors. *See id.* (noting that, in the context of patient safety, consumers – unlike investors – are not presumed to have knowledge of public information about a drug). Similarly, when the *NYT* article reiterated that the naproxen hypothesis was unproven and reported on the DDMAC letter, investors did not learn any “new” information that they did not have since March 2000, when the VIGOR results were released. Pivotaly, the DDMAC letter and the *NYT* article “did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis.” *Id.* Indeed, Merck continued to promote the naproxen hypothesis as the most likely explanation for the VIGOR results both in the *NYT* article and long afterwards. *See* Compl. ¶ 258. Thus, the court concluded, these documents were not storm warnings to a reasonable investor that Petitioners’ statements of opinion were not made in good faith. Pet. App. 43a.

The Third Circuit also held that a handful of pre-November 2001 consumer lawsuits by Vioxx users did not constitute storm warnings. *Id.* at 45a. These

suits “alleged that Merck failed to provide publicly available information to Vioxx consumers.” *Id.* Thus, the court determined that those lawsuits were irrelevant to the Complaint’s allegations that Petitioners fraudulently misstated their own opinions regarding the naproxen hypothesis to investors. *Id.* Finally, the Third Circuit noted that Merck’s stock price and analysts’ ratings and projections did not change at the time of the purported storm warnings. *Id.* at 44a-45a. The Third Circuit found that the lack of such changes, though not dispositive, indicated that financial markets did not view the DDMAC letter or the October 2001 *NYT* article as providing new, adverse information about Vioxx. *Id.*

The Third Circuit subsequently denied Petitioners’ request for rehearing *en banc*.

4. Respondents’ Superseding Amended Complaint.

Following the Third Circuit’s reversal, Respondents requested leave to amend their Complaint. Petitioners stipulated to the filing of the new complaint. On March 10, 2009, Respondents filed the new complaint, which reaffirms that the gravamen of Respondents’ claims is that Petitioners misled investors by publicly stating that they believed in the naproxen hypothesis when they actually believed that use of Vioxx caused serious cardiovascular harm. *See, e.g.*, Am. Compl. ¶¶ 10-15. Petitioners’ motion to dismiss the new, superseding complaint is due on April 17, 2009. The motion will be fully briefed by July 24, 2009.

REASONS FOR DENYING THE PETITION

Petitioners offer no persuasive reason for this Court to grant *certiorari*. There is no division among the circuits on the standard for when a plaintiff has a duty to investigate potential securities fraud or risk running afoul of the statute of limitations. Petitioners take issue with the Third Circuit’s application of that standard to Respondents’ then-operative Complaint and with the court’s interlocutory decision that Respondents did not receive “storm warnings” of the fraudulent scheme that they alleged. But that analysis, conducted on a Rule 12(b)(6) motion to dismiss, is fact-bound, and also of limited relevance given Respondents’ filing of a new, superseding complaint after the Third Circuit’s decision.

I. THIS CASE DOES NOT IMPLICATE ANY CONFLICT BETWEEN THE CIRCUITS.

As Petitioners concede, there is no circuit split regarding the first prong of the statute of limitations test: when sufficient “storm warnings” exist to trigger a duty to investigate possible fraud. *See* Pet. 3 (noting “general agreement” that no duty to investigate arises until a plaintiff has been “placed on notice of the possibility that it has been defrauded”). The purported division of authority that Petitioners seek to offer deals solely with the second prong of the standard: what actions by the plaintiff, *after* it is under a duty to investigate, affect the running of the limitations period. Because this second prong was not at issue below, the outcome in this case would be identical under any of the supposedly different approaches identified by Petitioners.

A. The Courts of Appeals Apply a Uniform Standard for What Triggers a Plaintiff's Duty To Investigate.

1. The circuits uniformly agree that "storm warnings" are necessary to trigger a duty to investigate.

As every Court of Appeals has recognized, to determine whether a plaintiff is on "inquiry notice" of securities fraud, courts ask whether there were sufficient suspicious facts to "lead a reasonable investor to check carefully into the possibility of fraud." *Young v. Lepone*, 305 F.3d 1, 8 (1st Cir. 2002). That concept – referred to as "storm warnings" – has become the uniform standard among the circuits for triggering inquiry notice. *Id.* (storm warnings analysis "necessarily entails a determination as to whether a harbinger, or series of harbingers, should have alerted a similarly situated investor that fraud was in the wind"); *accord Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 411 (2d Cir. 2008); *Merck, Pet. App.* 28a; *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993); *Sudo Props., Inc. v. Terrebonne Parish Consol. Gov't*, 503 F.3d 371, 376 (5th Cir. 2007); *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003) ("knowledge of suspicious facts – 'storm warnings,' they are frequently called – ... triggers a duty to investigate"); *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997); *Ritchey v. Horner*, 244 F.3d 635, 640-41 (8th Cir. 2001); *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 876 (9th Cir. 2008), *petition for cert. pending*, No. 07-1489 (U.S. filed May 27, 2008); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1203 (10th Cir. 1998); *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 968 (11th Cir.

2007) (“Inquiry notice ... occurs when there is factual evidence of the *possibility* of securities fraud that would cause a reasonable person to investigate whether his or her legal rights had been infringed.”).

Moreover, the Courts of Appeals have characterized the facts that constitute storm warnings similarly. The circuits agree that a plaintiff “need not ... have fully discovered the nature and extent of the fraud before [he was] on notice that something may have been amiss. Inquiry notice is triggered by evidence of the possibility of fraud, not full exposition of the scam itself.” *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987); *see also Staehr*, 547 F.3d at 411; *Brumbaugh*, 985 F.2d at 162 (same); *Fujisawa*, 115 F.3d at 1335 (same); *Tello*, 494 F.3d at 968 (same).⁶

Similarly, “[a]ll ... reported appellate cases are in accord” that, absent storm warnings, plaintiffs have no duty to investigate possible securities fraud claims, and thus cannot be on inquiry notice for pur-

⁶ The Third Circuit noted in *Merck* that it had characterized “storm warnings” in certain prior cases as “evidence alerting an investor to the *probability* of wrongdoing” and in others as “sufficient information of *possible* wrongdoing.” Pet. App. 28a. The Third Circuit found these differences to be largely semantic. *Id.* at 29a. It clarified that the underlying inquiry was “whether there was sufficient information of possible wrongdoing ... to excite storm warnings of culpable activity under the security laws” to a reasonable investor. *Id.* at 30a (internal quotation marks omitted). Only the Second Circuit articulates the “storm warnings” standard in terms of “probable,” rather than “possible.” *See Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 193 (2d Cir. 2003). This phraseology difference appears to involve semantics as well, and even Petitioners do not argue that the Second Circuit’s choice of words creates a split that this Court needs to resolve.

poses of the statute of limitations. *LaSalle v. Medco Research, Inc.*, 54 F.3d 443, 444 (7th Cir. 1995). Indeed, Petitioners concede that, under the inquiry notice standard “as typically applied,” a plaintiff does not have “a duty to investigate potential claims” until “placed on notice of the possibility that it has been defrauded.” Pet. 2-3.

2. The Third Circuit faithfully applied the settled law on “storm warnings.”

The Third Circuit applied this settled test for “storm warnings” below. The court held that the duty to investigate potential securities fraud does not begin “until a reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning,” and that “storm warnings” exist only if they “put [plaintiffs] on inquiry notice of actionable misrepresentations under the securities laws,” rather than some wrongdoing in the abstract. Pet. App. 22a, 35a (internal quotation marks omitted); *see also Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006). The Third Circuit held that “[p]laintiffs need not know all of the details or ‘narrow aspects’ of the alleged fraud to trigger the limitations period; instead, the period begins to run from the time at which plaintiff should have discovered the general fraudulent scheme.” Pet. App. 26a (internal quotation marks omitted; alteration in original).

The Third Circuit reasoned – consistent with every other circuit’s approach – that it had to determine whether “storm warnings” of “culpable activity” had arisen in the context of the securities laws violation alleged by Respondents. *See Lampf, Pleva,*

Lipkind, Prupis & Petigrow v. Gilbertson, 501 U.S. 350, 364 (1991) (suit “must be commenced within one year after the discovery of the facts *constituting the violation*”) (emphasis added). Here, the gravamen of Respondents’ claims is that Petitioners misled investors by stating their belief in the naproxen hypothesis when they did not honestly hold that belief. Thus, the Third Circuit explained that it had to “analyze the existence of storm warnings relative to th[e] allegation” that Merck fraudulently stated its belief in the naproxen hypothesis. Pet. App. 35a. The Court then determined whether, more than two years prior to the filing of Respondents’ initial complaint, there were any storm warnings that Merck did not genuinely hold its publicly stated belief in the naproxen hypothesis. The Third Circuit found there were no such storm warnings. *Id.* at 47a. In so finding, the court faithfully applied the uniform law of all circuits.

B. Petitioners Confuse Cases Concerning the Second Prong of the Limitations Test with Cases Implicating the First Prong Issue.

Petitioners assert that the Courts of Appeals use three different “approaches” for determining when the statute of limitations begins to run. Dispositively for this case, however, Petitioners’ analysis focuses on an alleged divide in the circuits’ application of the *second prong* of the statute of limitations test, which was not the basis for the judgment below.

1. Petitioners’ “three approaches” concern only the second prong, not the first.

Petitioners argue that, under what they term the “first approach,” the statute of limitations starts immediately after the plaintiff receives storm warnings

(Pet. 20); that under a “second approach” it starts once the plaintiff receives storm warnings and could have detected the fraud by exercising reasonable diligence (Pet. 21); and that the Third Circuit below and the Ninth Circuit in *Betz* follow a “third approach,” where the statute of limitations begins to run only after the plaintiff receives storm warnings and subsequently “stumbles upon” direct “evidence of scienter, materiality and loss causation” (Pet. 24).

Even under Petitioners’ own characterization of these approaches, none of them differs as to the first step in the analysis: whether sufficient “storm warnings” of the fraud exist in the first place to trigger the second prong requiring a plaintiff to investigate further. Only *after* the plaintiff receives storm warnings – and the first prong of the statute of limitations test is met – do the circuits purportedly employ differing tests to determine when the limitations period is commenced. Because the Third Circuit’s decision below rests entirely on applying the first prong of the statute of limitations test, Petitioners’ purported circuit conflict is irrelevant to resolving this case.

2. All of the circuits employ the same first prong test for “storm warnings.”

A review of the cases that Petitioners cite as evidence of the differing approaches to the *second* prong confirms that there is no circuit split as to the *first* prong. For example, Petitioners argue that the Fourth and Eleventh Circuits follow a “first” approach, while the First, Second, Sixth, Seventh, and Tenth Circuits follow a “second” approach. *See* Pet. 20, 21. But a review of *every* Fourth and Eleventh Circuit opinion cited by Petitioners shows that those cases adopt their inquiry notice standard – including their defini-

tion of “storm warnings” – from First and Seventh Circuit case law.⁷ *See, e.g., Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001) (adopting test in *Kauthar SDN BHD v. Sternberg*, 149 F.3d 659, 670 (7th Cir. 1998)); *Franze v. Equitable Assurance*, 296 F.3d 1250, 1254 (11th Cir. 2002) (citing *Theoharous*); *Brumbaugh*, 985 F.2d at 162 (adopting test in *Kennedy*, 814 F.2d at 802); *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 178 (4th Cir. 2007) (citing *Brumbaugh*).

Likewise, Petitioners argue that the Fifth and Eighth Circuits “sometimes” adopt the “first” approach. *See* Pet. 20-21. However, *every* Fifth and Eighth Circuit opinion cited by Petitioners adopts its test for storm warnings from First, Second, and Tenth Circuit case law, which purportedly follow the “second” approach. *See, e.g., Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988) (adopting test in *Armstrong v. McAlpin*, 699 F.2d 79, 88 (2d Cir. 1983), and *Cook v. Avien, Inc.*, 573 F.2d 685, 697-98 (1st Cir. 1978)); *Bodenhamer v. Shearson Lehman Hutton, Inc.*, No. 92-2392, 1993 WL 277033, at *2 (5th Cir. July 14, 1993) (judgment noted at 998 F.2d 1013) (citing *Jensen*); *Great Rivers Coop. v. Farmland Indus., Inc.*, 120 F.3d 893, 896 (8th Cir. 1997) (citing *Davidson v. Wilson*, 973 F.2d 1391, 1402 (8th Cir. 1992), which adopted the test in *Anixter v. Home-Stake Production Co.*, 939 F.2d 1420, 1437 (internal quotation marks omitted), *amended on other grounds on denial of*

⁷ At least one First Circuit case cited by Petitioners as falling under their so-called “second” approach explicitly adopts the Third Circuit’s statute of limitations test – which Petitioners assert falls under a “third approach.” *See Young*, 305 F.3d at 8 (adopting test in *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 251 n.14 (3d Cir. 2001)).

reh'g, 947 F.2d 897 (10th Cir. 1991), *vacated and remanded on other grounds sub nom. Dennler v. Trippet*, 503 U.S. 978 (1992), and *Cook*, 573 F.2d at 696-97).

Similarly, notwithstanding Petitioners' assertion that the Third Circuit in the present case and the Ninth Circuit in *Betz* adopted yet a third "approach," those decisions demonstrate that both courts enunciated and intended to apply the same standard for storm warnings as every other circuit. In *Betz*, the Ninth Circuit expressly adopted the same inquiry notice test that all other circuits apply: "[a] plaintiff is on inquiry notice when there exists sufficient suspicion of fraud to cause a reasonable investor to investigate the matter further." 519 F.3d at 876. Indeed, the Ninth Circuit specifically relied on and adopted the cases that, according to Petitioners, follow a conflicting approach. *Compare id.* at 876-77 (citing with approval *Sterlin*, *Fujisawa*, and *Great Rivers*) *with* Pet. 21-22 (arguing that the test in *Betz* differs from *Sterlin*, *Fujisawa*, and *Great Rivers*).

In the present case, the Third Circuit heavily relied on its prior decisions, *see* Pet. App. 23a-24a, 28a, which made clear that the court viewed "[t]he general articulation of the inquiry notice standard ... [a]s fairly consistent." *Mathews*, 260 F.3d at 251. The Third Circuit endorsed just that "consistent articulation" below by adopting the very cases that Petitioners cite as demonstrating a circuit split. *Compare id.* at 251 n.15 (citing *Great Rivers* as evidence that the Courts of Appeals use the same standard for inquiry notice) *with* Pet. 21 (citing *Great Rivers* as evidence that the Courts of Appeals do not use the same standard for inquiry notice); *compare also* Pet. App. 29a-30a (citing *Fujisawa* as using a

“similar[.]” test as the Third Circuit) *with* Pet. 22 (citing *Fujisawa* as using a different test from the Third Circuit).

C. Respondents’ Claims Would Be Timely Under Any of the Putatively Different Tests Proffered by Petitioners.

Because all the circuits use the same test to determine whether there are storm warnings of fraud, this case would not have come out differently in any other Court of Appeals.

Petitioners argue that, under the law of any circuit other than the Ninth and Third Circuits, plaintiffs’ claims would be untimely. *See* Pet. 25. That is incorrect. The Third Circuit found, as a factual matter, that there was no reason to suspect that Petitioners did not believe in the naproxen hypothesis until at least October 2003, when the results of the Brigham study were published. *See* Pet. App. 18a, 46a-47a. Because “market analysts, scientists, the press and even the FDA agreed that the naproxen hypothesis was plausible, at the very least,” *id.* at 46a, plaintiffs had no hint that Petitioners did not actually believe in their naproxen hypothesis.⁸ Without such storm

⁸ Petitioners complain that the Third Circuit adopted a new test for storm warnings in considering how Merck’s stock price was affected by various disclosures. *See* Pet. 24 n.9. However, the Third Circuit expressly stated the opposite, noting that it was not establishing a *per se* rule that storm warnings do not exist in the absence of declines in the stock price or analyst’s ratings. *See* Pet. App. 47a n.16. In an open market securities action, it is logical that the reaction of a company’s stock to news is a factual indicator of whether the information is new, material, or suspicious, and, thus, is relevant to whether information constitutes storm warnings. If the market or analysts do not react to information with suspicion, it follows that a reasonable investor generally would not either.

warnings, Respondents had no duty to investigate under any of the circuits' tests, and the statute of limitations was not triggered. *See LaSalle*, 54 F.3d at 444.

The Third Circuit below faced a question of first impression in applying the uniform inquiry notice standard to a claim that defendants had misrepresented their own opinion on a scientific issue. Applying the first prong of the statute of limitations test adopted by every circuit, the Third Circuit found that that prong could not be met until Respondents had some reason to believe Petitioners did not or could not believe that opinion when they offered it.

Petitioners argue that the Second Circuit would have decided this case differently, pointing to a district court decision in *In re Zyprexa Products Liability Litigation*, 549 F. Supp. 2d 496, 535-36 (E.D.N.Y. 2008), and the non-precedential decision in *Masters v. GlaxoSmithKline*, 271 F. App'x 46, 49 (2d Cir. 2008). *See* Pet. 26. However, the complaints in those cases dealt with misstatements of material fact, not with misstatements of opinion. Petitioners' argument rests on (a) repeating the District Court's mischaracterization of Respondents' claims and (b) assuming, counterfactually, that storm warnings existed. By publicly disclosing the results of the VIGOR trial, while simultaneously attributing those results to a hypothesis that even the FDA noted was a possible explanation of the VIGOR results – *but that Petitioners themselves believed to be false* – Petitioners avoided creating storm warnings of their misconduct. Because there were no storm warnings that Petitioners did not believe the naproxen hypothesis was true, under either Third or Second Circuit case law the statute of limitations was not triggered.

Petitioners also contend that this case would have come out differently in the First, Fifth, Sixth, Seventh, and Eighth Circuits because “[i]n these circuits ... the timeliness of respondents’ claims would depend upon the results of a reasonable diligent investigation.” Pet. 27. However, none of these circuits would have considered the “results of a reasonable diligent investigation” because none would have required a reasonable investor to conduct such an investigation in the absence of storm warnings.⁹

II. THE THIRD CIRCUIT’S INTERLOCUTORY ORDER IS CONSISTENT WITH THIS COURT’S DECISION IN *LAMPF*.

The Third Circuit’s decision comports with this Court’s opinion in *Lampf*, with the statute, and with the goals of inquiry notice. In *Lampf*, this Court held that “[l]itigation instituted pursuant to § 10(b) ... must be commenced within one year after the discovery of *the facts constituting the violation*.” 501 U.S. at 364 (emphasis added). The codification of the statute of limitations in § 1658(b) similarly states that an action may not be brought later than “2 years after the discovery of the *facts constituting the violation*.” 28 U.S.C. § 1658(b) (emphasis added). Thus, a proper analysis of the statute of limitations must take account of what “violation” is alleged.

Petitioners, like the District Court below, misapprehend the “violation” of the securities laws that Respondents allege, and thus confuse the issue of

⁹ Petitioners also assert that Respondents’ claims would have been time-barred in the Eleventh or Fourth Circuit. See Pet. 25. However, Petitioners do not explain why that is so and merely quote the inquiry notice test in those circuits – which use the same language as the Third Circuit below.

when a duty to investigate that potential violation arose. Petitioners assert that there were storm warnings that “petitioners made knowing misrepresentations regarding the safety of [Vioxx].” Pet. 4. However, as the Third Circuit recognized, Respondents’ “theory in the complaint is that Merck’s statements about the validity of the naproxen hypothesis were falsely-held statements of opinion or belief.” Pet. App. 33a-34a. *Lampf* and § 1658(b) require that any statute of limitations analysis take a proper understanding of the alleged fraud as its starting point. Petitioners’ attack on the Third Circuit’s opinion is off point because they address the wrong “violation.”

Given a proper understanding of Respondents’ claims, the Third Circuit’s decision clearly comports with the goals of inquiry notice. Inquiry notice exists to prevent an investor who suspects securities fraud from “sit[ting] back ... so that he could see how the price of his stock behaved in the interim.” *Fujisawa*, 115 F.3d at 1337; *accord Mathews*, 260 F.3d at 254. However, “[i]nquiry notice ... must not be construed so broadly that the statute of limitations starts running too soon for the victim of the fraud to be able to bring suit The facts constituting such notice must be sufficiently probative of fraud – sufficiently advanced beyond the stage of a mere suspicion.” *Fujisawa*, 115 F.3d at 1335; *see also Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1996) (same). That concern is particularly important with respect to the statute of limitations for securities fraud claims, which must meet the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 (“PSLRA”), 15 U.S.C. § 78u-4(b). *See* Pet. App. 30a.

Petitioners broadly suggest that hints of *any* misdeeds by a defendant – such as Merck’s inadequately balanced sales presentations at issue in the consumer lawsuits and the DDMAC’s warning letter – should trigger the statute of limitations for a securities fraud claim. *See* Pet. 30-31. However, there is no rule “that notice of one wrong by a defendant triggers a duty for potential plaintiffs to investigate all other potential wrongs the defendant might be committing.” *Morton’s Market, Inc. v. Gustafson’s Dairy, Inc.*, 198 F.3d 823, 834 (1999), *amended in part on other grounds*, 211 F.3d 1224 (11th Cir. 2000); *see also La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 848 (11th Cir. 2004) (same); *cf. Marine Bank v. Weaver*, 455 U.S. 551, 556 (1982) (“Congress, in enacting the securities laws, did not intend to provide a broad federal remedy for all fraud.”). The inquiry notice standard does not require investors to launch a wild-goose chase for evidence of securities fraud simply because they receive hints that a defendant has committed a different type of wrongdoing (*e.g.*, has run afoul of laws regulating the safety of products or has provided inadequate warnings to consumers of a drug).

Petitioners’ other arguments that the Third Circuit’s decision frustrates the policy behind the statute of limitations likewise fail.

First, Petitioners contend that the Third Circuit’s decision removes the “investigation” step from the statute of limitations test. *See* Pet. 28. That is incorrect. The Third Circuit never reached the investigative step under the facts of this case because there were no storm warnings to prompt an inquiry or investigation in the first place. The two-pronged statute of limitations test only requires the investor

to investigate if there is adequate reason – namely, storm warnings – to do so.

Second, Petitioners claim that the Third Circuit’s decision encourages plaintiffs to disregard storm warnings. *See* Pet. 29. Again, that is incorrect: the Third Circuit found that there were no storm warnings, and its decision has no bearing on what an investor should have done had there been such warnings.

Third, Petitioners complain that the Third Circuit’s decision forces defendants to choose between arguing that the plaintiff had sufficient evidence of fraud to trigger the duty to investigate and arguing that the plaintiff has insufficient evidence to bring a claim under Rule 12(b)(6). *See* Pet. 29-30. Of course, defendants can and regularly do make both arguments in the alternative. In any event, that tension is inherent between *any* inquiry notice standard and Rule 12(b)(6).

III. THIS CASE IS FACT-BOUND AND, IN ANY EVENT, THE DISTRICT COURT SHOULD BE PERMITTED IN THE FIRST INSTANCE TO EVALUATE STATUTE OF LIMITATIONS ARGUMENTS UNDER THE NEW COMPLAINT.

The decision below did not turn on the appropriate legal standard for inquiry notice. Rather, it was based on a detailed factual analysis of the information available to Respondents and of Respondents’ Complaint. Indeed, the latter analysis may be moot because Respondents have since filed a new complaint.

A. The Third Circuit’s Decision To Reverse the District Court Turned on the Specific Facts Surrounding Respondents’ Claims, Not on the Inquiry Notice Standard.

Importantly, in reaching contrary conclusions, the Third Circuit and the District Court did *not* disagree on the legal standard for inquiry notice. *Compare* Pet. App. 83a-84a *with id.* at 23a-24a. The District Court came to an incorrect result because it misapprehended the nature of Respondents’ claims and, therefore, misunderstood the import of information surrounding the VIGOR trial. The two courts disagreed in their fact-bound interpretations of Respondents’ Complaint and in their assessment of the very different claims that they perceived Respondents to have made against the publicly available information. *See id.* at 31a-47a (applying the inquiry notice standard to the publicly available information).

The Courts of Appeals agree that “[t]he determination of *when* inquiry notice occurred ... [is] necessarily fact-specific to each case.” *Tello v. Dean Witter Reynolds, Inc.*, 410 F.3d 1275, 1284 (11th Cir. 2005); *see also Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 169 (2d Cir. 2005) (“Our recent decisions reinforce the fact-specific nature of the limitations defense, particularly where the claim is foreclosed by inquiry notice.”); *Young*, 305 F.3d at 9 (“The multifaceted question of whether storm warnings were apparent involves issues of fact. In the archetypical case, therefore, it is for the factfinder to determine whether a particular collection of data was sufficiently aposematic to place an investor on inquiry notice.”) (citation omitted). This case, in particular, hinges not on any question relating to the legal standard for inquiry notice, but instead on the proper characterization of Respondents’ factual allegations.

B. Petitioners Have Consented to the Filing of Respondents' Amended Complaint, So the District Court Should Analyze Any Remaining Statute of Limitations Arguments in the First Instance.

The District Court initially erred in finding storm warnings of securities fraud because it misinterpreted Respondents' Complaint. While the Third Circuit correctly held that Respondents alleged fraudulent statements of opinion, Respondents filed a new Complaint on March 10, 2009, that clearly alleges that Petitioners made false statements of opinion when they expressed their belief in the naproxen hypothesis. *See* Am. Compl. ¶ 145. Petitioners consented to the filing of the Amended Complaint. The lower court decisions were predicated on Respondents' prior Complaint dated June 14, 2005. The operative complaint in the case has subsequently changed – without Petitioners' opposition. Therefore, it should be the District Court in the first instance that rules on whether Respondents' operative complaint is barred by the statute of limitations. *See, e.g., Vega-Encarnación v. Babilonia*, 344 F.3d 37, 42 (1st Cir. 2003) (“The limitations defense ... should be addressed in the first instance in the district court.”).¹⁰

IV. THE SPECIFIC STATUTE OF LIMITATIONS QUESTION PRESENTED BELOW WILL RARELY RECUR.

Any decision by this Court to address the standards for inquiry notice ought to involve a recurring fact pattern. The decision below arose in the unusual

¹⁰ The briefing schedule for Petitioners' motion to dismiss the superseding Amended Complaint is noted at page 13 above.

context of a securities fraud claim based on a misrepresentation of an *opinion*. In this case (1) Petitioners disclosed the results of the VIGOR trial even though one interpretation of the study called into question Vioxx's safety; (2) there was a scientific debate among third parties – including doctors and the FDA – over whether the results of the VIGOR trial were attributable to the cardio-protective effects of naproxen or the adverse effects of Vioxx; and (3) Petitioners publicly stated their belief that the naproxen hypothesis was correct, even though they had reached a contrary conclusion internally and did not genuinely hold that belief.

In sum, Respondents alleged that Petitioners made false statements of opinion concerning a hypothesis that they did not believe was true, in circumstances where third parties (doubtless influenced by Merck) subsequently embraced that hypothesis. This unusual constellation of circumstances arose in part because of the complexity of the underlying scientific question on which Petitioners stated their opinion, as well as the lack of definitive public studies of Vioxx and naproxen's effects on cardiovascular events. Respondents are aware of no securities fraud case outside the Third Circuit analyzing storm warnings in an analogous context.¹¹ Thus, there is no division

¹¹ A recent Third Circuit case, *Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 347 (3d Cir. 2009), also involves “interpretation” of clinical trial results and a claim that the defendant fraudulently misstated its own opinion. There, the court considered whether plaintiffs were put on inquiry notice that drugmaker Pharmacia had engaged in culpable activity where information provided at a public FDA meeting confirmed that Pharmacia had not disclosed certain clinical study data, but where there was no suggestion that Pharmacia did not believe its publicly stated opinion that it had properly

of authority in the circuits on how the inquiry notice standard applies to misstatements of opinion. Moreover, the lack of a developed jurisprudence in this context suggests that this case involves an unusual fact pattern and that the petition raises questions of narrow applicability.

In any event, Petitioners wrongly assert that this case underscores the lack of uniformity among the

excluded those data for valid scientific reasons. *Id.* at 349. In that factual context, the Third Circuit held that “[t]he mere fact ... that there was a technical dispute between scientists about whether to use the full data or only a portion of the data, would not have provided storm warnings of fraud to the reasonable investor,” *id.* at 350, and that, for storm warnings, “there must be *some indication* that defendants did not, in fact, hold the views expressed,” *id.* at 348 (emphasis added). The court did not find the requisite “some indication” until a later *Washington Post* article suggested that Pharmacia had “massaged” certain trial data and also withheld information from the medical journal that published an article on the trial’s findings. Although the *Pharmacia* opinion states that “*Merck* found that inquiry notice ... requires storm warnings indicating that defendants acted with scienter,” *id.*, the *Merck* decision never used that language. Read in context, *Pharmacia*’s use of the term “scienter” was shorthand for its application of the false opinion/inquiry notice test actually employed in *Merck*, which *Pharmacia* then accurately quotes: “[T]o trigger storm warnings of culpable activity, in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, i.e., *that they did not hold those opinions or beliefs in earnest.*” *Id.* (quoting Pet. App. 33a). Thus, to find “storm warnings,” *Pharmacia* ultimately required only “some indication” of a “possibility of fraud,” *id.* at 350, and certainly not the quantum of evidence that would enable a plaintiff to plead scienter under the PSLRA. *See, e.g., id.* at 351 n.10 (“We note that inquiry notice ... is alive and well in this Court. ... Here, we merely conclude that, in the absence of *any indication* that defendants did not believe the truth of their own statements, investors were not on inquiry notice of § 10(b) claims.”) (emphasis added).

circuits on the standard for inquiry notice. *See* Pet. 32. Each Court of Appeals employs the same test to determine if storm warnings are present and the duty to investigate is triggered. *See* pp. 15-16, *supra*. Petitioners essentially assert that, on the very same facts, the case would have come out differently in some other court. But there is no basis for thinking that the Courts of Appeals do not apply the same legal standard in the same way. *See Tello*, 410 F.3d at 1284.

V. THIS CASE NEED NOT BE HELD FOR *BETZ*.

This Court has invited the Solicitor General to file a brief expressing the views of the United States on the pending petition for *certiorari* in *Betz*. *See Trainer Wortham & Co. v. Betz*, No. 07-1489 (U.S. filed May 27, 2008). There is no need to hold this case pending any decision by the Court in *Betz*.

Betz articulated the first prong of the statute of limitations test in the same manner as every other circuit. *See* p. 15, *supra*. Even Judge Kozinski, in dissenting from the denial of rehearing *en banc* in *Betz*, agreed that the Courts of Appeals have adopted a uniform standard with respect to the type of information that puts a plaintiff on notice: “[a]ccording to the same ten circuits, the statute of limitations starts to run ... when a reasonable investor in plaintiff’s position would suspect he had been defrauded.” 519 F.3d at 866. Judge Kozinski took issue not with that standard – which *Betz* explicitly adopted – but rather with the application of that standard to the facts in *Betz*. *See id.* (“The panel pretends to adopt this standard, but rejects it in fact.”). Because the particular manner in which the *Betz* panel applied that univer-

sal standard to the facts before it has no bearing on the Third Circuit's application of the standard to the different – and unusual – facts of this case, there is no reason to hold this case for *Betz*.

CONCLUSION

The petition for a writ of *certiorari* should be denied.

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