No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., et al.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Ninth Circuit

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Court of Appeals correctly held that the district court's reliance upon a singular "statistical significance" standard in order to assess the materiality of petitioners' misstatements and omissions was inconsistent with this Court's decision in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), rejecting bright-line materiality rules.

2. Whether the Court of Appeals correctly held that, in considering all of the alleged facts together and taking them to be true, the Complaint's allegations gave rise to a strong inference of scienter that was cogent and at least as compelling as any opposing inference drawn from the facts alleged.

RULE 29.6 DISCLOSURE

Neither James Siracusano nor NECA-IBEW Pension Fund is a corporation.

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I. STATEMENT OF THE CASE

A. Matrixx's Core Business: the Zicam Cold Remedy

Petitioner Matrixx develops, manufactures, and markets over-the-counter pharmaceuticals. ER68:¶2.[1] Matrixx's core brand during the Class Period – through its wholly-owned subsidiary Zicam, LLC – was a line of common-cold products comprising 100% of Matrixx's sales,

[1] Citations to "ER___" are to the Excerpts of Record filed in the Ninth Circuit Court of Appeals; citations to "App. __" are to the Appendix filed by petitioners. Because the appeals court's opinion does not necessarily list all relevant record facts, respondents will supplement their Appendix cites when required with citations to the operative Complaint ("ER68:¶__").

gross profits, and growth. *Id.*; App. 2a. Within that core product line, "Zicam Cold Remedy" (hereafter "Zicam") accounted for approximately 70% of sales overall. App. 4a. The cold remedy could be applied in several forms, including a nasal spray and nasal gel. *Id.*

It is that intranasal version of Zicam that lies at the center of this action.

B. Petitioners Received Repeated Warnings from Olfactory Medical Researchers and Complaints from Zicam Users that Zicam Caused a Horrific Side Effect Called "Anosmia" – Loss of Sense of Smell – in Numerous Users

Both before and during the Class Period, petitioners received numerous warnings that Zicam nasal gel use was being linked to the loss of sense of smell in some users.

1. Dr. Alan Hirsch, Neurological Director of the Smell & Taste Treatment and Research Foundation, Warned Matrixx in December 1999 About a Zicam-Anosmia Link

In 1999, Dr. Alan Hirsch, M.D., F.A.C.P., recognized a possible link between Zicam nasal gel and loss of smell in "a cluster" of his patients. ER68:¶25; App. 4a-5a. In December 1999 – nearly four years before the Class Period began – Dr. Hirsch called Matrixx's customer service line to inquire about the amount of zinc in Zicam's nasal gel. App. 4a-5a. Dr. Hirsch reported to Matrixx that one of his patients had developed anosmia after using Zicam, and noted that there existed studies demonstrating problems associated with the intranasal application of zinc. App. 5a. Dr. Hirsch volunteered to conduct a clinical study on the possible Zicam-anosmia link, but was turned down. *Id.*

2. Petitioner Clarot Approached Dr. Miriam Linschoten of the University of Colorado's Health Sciences Center and the Rocky Mountain Taste and Smell Center ("RMTSC") in 2002, and Discussed with Her Complaints Matrixx Had Received Concerning the Link Between Zicam Use and Anosmia

Petitioner Timothy Clarot, Matrixx's Vice President of Research and Development, reached out to Dr. Linschoten in September 2002 concerning Zicam's link with anosmia. App. 5a. Clarot had called Dr. Linschoten because one of the several patients she had been treating at the RMTSC for loss of smell following Zicam use had also complained to Matrixx. *Id.* Clarot admitted to Dr. Linschoten that Matrixx had received *additional* similar complaints from other Zicam nasal gel consumers. *Id.* In fact, Matrixx had been receiving those complaints as far back as 1999. *Id.*

Dr. Linschoten followed up Clarot's call by e-mailing him several abstracts on the link between zinc sulfate and anosmia – pointing out that zinc's toxicity had been confirmed by studies dating back to the 1930s. *Id.* In response, Clarot telephoned her again, and invited her to participate in some upcoming animal studies Matrixx was planning. *Id.* Dr. Linschoten declined, explaining that her focus was on human research. *Id.*

3. Dr. Bruce Jafek, in the Department of Otolaryngology at the University of Colorado School of Medicine, Prepared a Medical-Conference Presentation in Fall 2003 that Described Ten Cases of Zicam-Linked Anosmia – and in Response Matrixx Warned Him Against Identifying Zicam

As of September 2003 – just one month before the Class Period – Dr. Jafek had observed ten patients suffering from anosmia following Zicam use. App. 5a-6a. Together with Dr. Linschoten and a second colleague (Bruce Murrow, also from Colorado's Department of Otolaryngology[2] (ER68:¶64)), Dr. Jafek planned to submit the trio's findings via a September 20, 2003 poster presentation to the American Rhinologic Society. App. 5a-6a. Prior to the September conference, the Society posted the scheduled presentations in abstract form. ER68:¶28. The abstract for the Jafek-Linschoten-Murrow presentation was entitled "Zicam® Induced Anosmia." *Id.*

The trio's research included a detailed description of a 55-year-old man who, prior to using Zicam, had normal taste and smell function. *Id.* Upon spraying Zicam into his nose, however, the subject experienced severe burning that was followed immediately by the loss of his sense of smell. *Id.* The Colorado researchers reported "10 [*sic*] other Zicam users with similar symptoms." *Id.*[3]

Before the researchers could make their formal presentation, on September 12, 2003, Matrixx sent a letter to Dr. Jafek – signed by petitioner Clarot – informing him that he could not name either Matrixx or its products on the poster. ER68:¶29; App. 6a. After consulting with the University of Colorado's attorney, Dr. Jafek sought Matrixx's permission to use the names – which Matrixx denied in a second letter. ER68:¶29. Dr. Jafek then cut

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[2] Otolaryngologists are "physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck." *See* the American Academy of Otolaryngology's Web site at http://www.entnet.org/healthinformation/AboutOtolaryngology.cfm.

[3] The Complaint contains a typo, and should have stated that the researchers reported "9 other Zicam users," for a total of 10.

out all instances of the word "Zicam" from the poster, and presented it to the Society in redacted form. *Id.*; App. 6a, 19a.

4. Numerous Zicam Users Filed Personal Injury Lawsuits Against Matrixx, Complaining that Zicam Caused Their Loss of Sense of Smell

Beginning just before and continuing throughout the three-and-a-half-month Class Period, nine Zicam users sued Matrixx for personal injuries – alleging that Zicam had damaged their sense of smell. ER68:¶49; App. 32a.

- On October 14, 2003, two plaintiffs sued Matrixx in Michigan federal court, in *Christensen, et al. v. Matrixx Initiatives, Inc., et al.*, No. 4:03-cv-0146-HWB (W.D. Mich.). ER68:¶49.
- On December 8, 2003, a plaintiff sued Matrixx in California state court, in *Nelson v. Matrixx Initiatives, Inc., et al.*, No. YC048136 (Cal. Super. Ct. – Los Angeles). *Id.*
- On December 18, 2003, a plaintiff sued Matrixx in Alabama state court, in *Sutherland v. Matrixx Initiatives, Inc., et al.*, No. CV2003-1635-WHR (Ala. Cir. Ct. – Etowah). *Id.* The case was later removed to Alabama federal court (No. 4:2004cv00129 (N.D. Ala.). *Id.*
- On January 23, 2004, five plaintiffs sued Matrixx in Arizona state court, in *Bentley, et al. v. Matrixx Initiatives, Inc., et al.*, No. CV2004-001338 (Ariz. Super. Ct. – Maricopa). *Id.* The number of plaintiffs in *Bentley* eventually grew to 266, through consolidation of later suits. *Id.*

The foregoing lawsuits were just the Zicam-related personal injury actions filed before the Class Period's end

on February 6, 2004 – at which point Matrixx was still insisting that Zicam was perfectly safe. ER68:¶44; App. 13a-14a. Matrixx's Securities and Exchange Commission ("SEC") filings later revealed that from late 2003 through October 2004, over 280 individuals sued Matrixx, alleging that Zicam had damaged their sense of smell. App. 16a.

C. Despite the Foregoing, Petitioners Made a Series of False and Misleading Public Reassurances Concerning Zicam's Supposed Safety

Throughout the Class Period, Petitioners issued a series of false and misleading statements concerning Zicam's safety, and what the Zicam product line portended for Matrixx's financial success. ER68:¶¶32-41; App. 6a-14a. The Zicam brand was "poised for growth" in the upcoming cough and cold season, for Matrixx's retail partners had come to rely on the Zicam brand as "an efficacious product." App. 6a-7a. The driving force behind Matrixx's "very strong momentum" heading into the season was the Zicam product line – "a product that offers a unique benefit." App. 7a. Revenues for the full year were poised to rise dramatically, "up in excess of 50%." *Id.*

Notably, on November 12, 2003, Matrixx formally filed its third-quarter 2003 financial results on Form 10-Q with the SEC. App. 8a. Petitioners Johnson and Hemelt both signed the filing. ER68:¶35. Although the *Christensen* lawsuit accusing Zicam of causing anosmia had already been filed the previous month (ER68:¶49), Matrixx's November filing omitted that fact. ER68:¶35; App. 9a.

Instead, Matrixx simply warned investors of the reputational and financial consequences from a *potential* product-liability claim against it – even if the claim was without merit:

> A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

App. 9a. Johnson and Hemelt also signed the quarterly report's certification pursuant to §302 of the Sarbanes-Oxley Act of 2002, asserting that the report did not contain any untrue statements of material fact "or omit to state a material fact necessary to make the statements made" not misleading. ER68:¶36.

D. As Complaints Surfaced About Zicam-Caused Anosmia, Matrixx Went on the Offensive – Vehemently (and Falsely) Denying Any Link Between Zicam and Loss of Sense of Smell

On January 30, 2004, after the close of ordinary trading, the Dow Jones Newswires reported that the Food and Drug Administration ("FDA") was looking into complaints that "an over-the-counter common-cold medicine manufactured" by a Matrixx unit "may be causing some users to lose their sense of smell." App. 10a. Dow Jones noted that the allegations had been made in "at least three lawsuits." *Id.* In fact, by the time of the January 30 Dow Jones piece, ***four*** Zicam-related lawsuits had been filed against Matrixx by nine plaintiffs. ER68:¶49. Following the Dow Jones revelation, Matrixx's stock price dropped from $13.55 per share on January 30, 2004, to $11.97 per share on February 2, 2004. App. 10a.

Matrixx responded to the Dow Jones piece with a

February 2 press release denying any Zicam-anosmia connection. App. 10a-11a. Any statements "alleging that intranasal Zicam products cause anosmia (loss of smell)," blasted Matrixx, "*are completely unfounded and misleading.*" App. 10a (emphasis added). Indeed, "*[i]n no clinical trial* of intranasal zinc gluconate gel products *has there been a single report* of lost or diminished olfactory function (sense of smell). Rather, the *safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established* in two double-blind, placebo-controlled, randomized clinical trials." App. 11a (emphasis added). Matrixx suggested the blame might lie elsewhere, as a "multitude of environmental and biologic influences are known to affect the sense of smell." *Id.*

Following Matrixx's denials, its stock price rose back to $13.40 on February 3. App. 13a.

E. Once the Dramatic Truth About Zicam's Link to Loss of Sense of Smell Was Revealed to a Nationwide Audience, Matrixx's Stock Price Plummeted

On February 6, 2004, the link between Zicam and anosmia was revealed to a nationwide television audience. App. 13a. On the news program *Good Morning America* that day, reporter John Ferrugia told viewers about a woman named "Linda" who claimed that Zicam gel had caused her anosmia. ER68:¶42; App. 13a. Ferrugia noted that Linda's claim was not an isolated one: "Dr. Bruce Jafek has discovered more than a dozen patients with the same troubles as Linda . . . after using the Zicam product." ER68:¶42. The reporter also tallied the burgeoning number of lawsuits against Matrixx alleging Zicam-caused anosmia: "[I]n fact, there have been, so far, four lawsuits." *Id.* But those four were not the only ones on the horizon, as "[o]thers are being prepared, anywhere from California to Michigan." *Id.*

Petitioners continued to obfuscate and deny. That same day, Matrixx issued another press release entitled "Reaffirm[ing] Safety of Intranasal Zicam® Remedy," and insisted that any reports linking anosmia with Zicam were "completely unfounded and misleading." ER68:¶44; App. 13a. "In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell)." App. 13a.

Petitioners' denials did not work this time. Following the *Good Morning America* piece, Matrixx's common stock plummeted from the previous day's $13.05 per share to close at $9.94, on unusually heavy trading volume. ER68:¶43. Investors saw nearly one-quarter of their Matrixx stock value erased, for the plunge represented a one-day drop of 23.8%. *Id.*; App. 13a.

F. Epilogue: Petitioners' Post-Class Period Admissions Contradicted Their Earlier Representations, While the Numbers of Zicam-Related Anosmia Sufferers Climbed Even Higher

In a stunning turnaround from its insistence two weeks earlier that any alleged links between Zicam and anosmia were "completely unfounded and misleading," on February 19, 2004, Matrixx admitted that it simply *did not know* whether or not Zicam could cause loss of sense of smell. ER68:¶¶45-46; App. 14a-15a.

The admission came in a Form 8-K filed with the SEC, in which Matrixx explained that it had convened a two-day meeting of "physicians and scientists to review current information on smell disorders" as a direct response to "a poster presentation at the American Rhinological [*sic*] Society in September 2003." ER68:¶45; App. 14a. The Matrixx-convened panel concluded that there was "*insufficient scientific evidence at this time to deter-*

mine if zinc gluconate, when used as recommended, *affects a person's ability to smell.*" App. 15a (emphasis added). As reporter John Ferrugia noted in a followup report: "All along, Matrixx Initiatives, the maker of Zicam, said the product was safe. But now it admits there are no studies dealing with the issue." ER68:¶47; App. 15a.

As the underlying matter was pending, the FDA issued a warning letter to Matrixx on June 16, 2009, explaining that several Zicam products "may pose a serious risk to consumers who use them."[4] The FDA had received "more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products." *Id.* Directly contradicting petitioners' claims of clinical studies establishing Zicam's safety, the FDA noted: "*We are not aware of any data* establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling. [footnote omitted] *On the contrary*, as described below, *there is evidence that these products pose a serious safety risk to consumers.*" *Id.* (emphasis added).

II. REASONS FOR DENYING THE PETITION

In order to adequately allege a private securities-fraud violation under §10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance (or "transaction causation"); (5) economic loss; and (6) loss causation. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005).

The district court dismissed respondents' Complaint solely on the grounds that the first two elements had been

[4] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm.

inadequately alleged.[5] And, as petitioners admit, those two holdings were based upon a single, overlapping rationale: the district court's utilization of a "*statistical significance standard* as a measure of both materiality and scienter." Pet. 5 (emphasis added).

It is that concept of "statistical significance" that the Ninth Circuit correctly rejected as a singular requirement for materiality – harkening to this Court's rule in *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988). And, in the Circuit's scienter holding (*see infra* §II.D.), the panel focused on the totality of the Complaint's allegations while answering the question of whether the resulting scienter inference was cogent and at least as compelling as any opposing inference drawn from the facts alleged – just as this Court counsels. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 311 (2007).

A. The Ninth Circuit's Refusal to Apply a Bright-Line Materiality Test Faithfully Comports with This Court's Holding in *Basic Inc. v. Levinson*

Faced with a district-court decision requiring that the "materiality" element of a securities-fraud claim be supported by "statistically significant" information, the Ninth Circuit looked to established materiality precedent while rejecting that bright-line approach. App. 21a-26a.

The *Matrixx* panel explained that this Court in *Basic* "rejected the adoption of a bright-line rule to determine materiality because "'[t]he determination [of materiality] requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts

[5] Because the district court's dismissal hinged on just materiality and scienter, the Ninth Circuit confined its analysis to those two elements. App. 21a.

and the significance of those inferences to him."'" App. 23a (quoting *Basic*, 485 U.S. at 236 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)) (second alteration in original)). Instead, courts assessing materiality should engage in a "'fact-specific inquiry.'" App. 23a (quoting *Basic*, 485 U.S. at 240).[6]

Thus, a correct analysis of materiality on the facts alleged here asks whether "'a reasonable shareholder would consider it important'" that large numbers of Zicam users had lost their sense of smell – *i.e.*, whether that fact "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus.*, 426 U.S. at 449). The Ninth Circuit answered this question in the affirmative, compiling the myriad undisclosed facts about a Zicam-anosmia link that a reasonable investor likely would have considered significant. App. 24a-26a.

Despite the foregoing, petitioners misread *Basic* and suggest that this Court erected its bright-line exclusion only in *that* case. Pet. 14 ("But the Court in *Basic* rejected the bright-line rule *proposed in that case* because it was based on policy considerations" not tied to the significance of the information for investors.) (emphasis added). That is not what this Court said, however; it explained that "*[a]ny* approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be over- or underinclusive." *Basic*, 485 U.S. at 236 (emphasis added).

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[6] Indeed, "'[d]etermining materiality in securities fraud cases "should ordinarily be left to the trier of fact."'" App. 23a (citations omitted); *see also Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 735 (7th Cir. 2004) (Easterbrook, J.) ("inappropriate to entertain" defendants' immateriality argument at the pleading stage).

That incorrect approach is precisely the one the district court took with its singular focus on the concept of "statistical significance," and the Ninth Circuit correctly rejected it. The Ninth Circuit's holding faithfully follows *Basic*, making review here unnecessary.

B. Petitioners' Supposed Circuit Split Concerning the Relationship Between Materiality and Statistical Significance Is Illusory

Positioning the Ninth Circuit's rejection of requiring statistical significance for materiality as an outlier holding, petitioners claim that three other circuits "have adopted" what they call a "statistical significance standard": the First Circuit in *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); the Second Circuit in the *Carter-Wallace* cases; and the Third Circuit in *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000). Pet. 7-10. Upon closer scrutiny, however, the "standard" applied by those circuits does nothing to undermine the Ninth Circuit's rejection of a bright-line approach as applied to materiality.

In *Biogen*, when the First Circuit mentioned the notion of "statistical significance," it was not addressing it in the context of materiality like the Ninth Circuit had; rather, it was conducting a case-specific, fact-specific *scienter* inquiry. *See Biogen*, 537 F.3d at 47 ("Even if plaintiffs met the standard of showing a *material* misrepresentation or omission, *as we assume arguendo they did*, they must still allege facts giving rise to a 'strong inference' of scienter.") (emphasis added). The Ninth Circuit's scienter inquiry here, in contrast, followed *Tellabs*'s totality-of-the-circumstances approach, and so did not even address "statistical significance" in that portion of its opinion. *See infra* §II.D.; *see* App. 26a-34a. *Biogen* thus is, simply and

starkly, inapposite to the Ninth Circuit's materiality holding that petitioners challenge.

Similarly, in *Carter-Wallace*, the sole issue again was scienter; the panel noted that the defendants had *conceded* all of the other elements of a securities-fraud claim. *See In re Carter-Wallace Sec. Litig.* ("*Carter-Wallace II*"), 220 F.3d 36, 39 (2d Cir. 2000) ("For purposes of its motion [for judgment on the pleadings], Carter-Wallace has conceded *all of the elements* of the appellants' claim *except scienter*.") (emphasis added). Thus, with materiality conceded, there was no need for the Second Circuit to hold that "statistical significance" was a prerequisite to finding materiality.

Notably, petitioners omit that the Second Circuit subscribes to the same view as the Ninth Circuit when it comes to materiality: that a "bright-line" materiality standard is at odds with this Court's teachings in *Basic*. *See, e.g.*, *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (agreeing with plaintiffs and the SEC as *amicus curiae* that the district "court's exclusive reliance on a single numerical or percentage benchmark to determine materiality was error"). *Ganino* notes there is "ample authority" supporting that narrow view of materiality as error – and pointedly cites to *Basic*. *See id.* (citing *Basic*, 485 U.S. at 236 & n.14).

Finally, although the Third Circuit in *Oran* did discuss statistical significance in connection with materiality, *Oran*'s materiality holding turned primarily on the lack of stock-price movement there in connection with allegedly material disclosures. Because defendants' disclosure of certain (allegedly damaging) data "had no appreciable negative effect on the company's stock price" – indeed, the stock actually rose in the days following the disclosure – "this price stability *is dispositive* of the question of materiality." *Oran*, 226 F.3d at 283 (emphasis added).

Oran went on to discuss "statistical significance" in connection with the materiality of other undisclosed data and adverse-reaction reports, but its reliance upon *Carter-Wallace* for the point shows that it – like petitioners here – misunderstood *Carter-Wallace* as constructing a statistical-significance/materiality regime.[7] The Third Circuit has since confirmed that *Oran*'s "materiality" holding is a stock-price-movement inquiry. *See In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (describing the "*Oran-Burlington* standard" as one in which the materiality of disclosed information may be measured *post hoc* by looking to stock-price movement in the period immediately following disclosure).

Plainly, the Ninth Circuit did not reject the idea of "statistical significance" *generally*, as petitioners would have this Court believe. Rather, the *Matrixx* panel simply held that the district court's substitution of a singular benchmark in place of the nuanced materiality inquiry described in *Basic* was reversible error. *See* App. 23a ("We conclude, however, that the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality."). That holding, far from conflicting with other circuits' view of materiality, actually comports with them. *See, e.g., Ganino*, 228 F.3d at 162 ("exclusive reliance on a single numerical or percentage benchmark to determine materiality was error"); *Martinez v. Schlumberger, Ltd.*,

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[7] Moreover, *Oran*'s conclusion that withheld data and adverse-reaction reports could not – *as a matter of law, no less* – be material to investors unless deemed statistically significant (226 F.3d at 284) directly contradicts this Court's holding in *Basic*. *Cf. Basic*, 485 U.S. at 236 ("Any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be over- or underinclusive."). Thus, it is *Oran* that appears to be the outlier on materiality, not *Matrixx*.

338 F.3d 407, 428 (5th Cir. 2003) ("*Basic* suggests that we are not to rely on a bright-line test to determine whether a company's alleged misrepresentations are material."); *Kurz v. Philadelphia Elec. Co.*, 994 F.2d 136, 139 (3d Cir. 1993) (citing *Basic*, and rejecting bright-line materiality rule suggested by defendant even though it "would be easier to administer"); *Rowe v. Maremont Corp.*, 850 F.2d 1226, 1234 (7th Cir. 1988) ("Materiality is necessarily a fact-specific inquiry, so 'any approach that designates a single fact or occurrence determinative of . . . materiality must necessarily be over- or underinclusive.'") (quoting *Basic*, 485 U.S. at 236).

Petitioners' circuit split is illusory.

C. The Fact-Bound Nature of the Panel's Materiality Holding Further Counsels Against Review

Review by this Court is also unwarranted because of the fact-bound nature of the decision below. In considering this premise, respondents respectfully suggest, it is important to keep in mind what the panel's statistical-significance holding is about – and more importantly, what it is *not* about.

At its core, the Ninth Circuit's decision concerned the materiality of information that petitioners failed to disclose to investors even while speaking constantly to the market about Zicam. That specific information – the horrific, life-altering injuries striking a number of Zicam users immediately after they used the product – came into Matrixx's executive suites through a variety of channels: otolaryngology researchers, consumer complaints, and personal-injury lawsuits. And yet during the Class Period petitioners misled investors, insisting that Zicam's safety and efficacy had been well established in clinical trials, and denying any asserted link between Zicam and

anosmia as "*completely unfounded and misleading.*" App. 10a (emphasis added). Despite having been sued in October 2003 for Zicam-induced anosmia (App. 25a), Matrixx's November 2003 SEC filings omitted that material fact – warning only that: "We may incur significant costs resulting from product liability claims." App. 8a. Before the end of the Class Period, three similar lawsuits had been filed against petitioners by seven additional plaintiffs. App. 25a-26a. After the Class Period, petitioners *admitted* that there was "*insufficient evidence at this time to determine if [Zicam]*, when used as recommended, *affects a person's ability to smell.*" ER68:¶46; App. 14a-15a (emphasis added). And yet during the Class Period petitioners had reassured investors that the "safety and efficacy" of Zicam had already been "well established" in clinical trials. App. 11a, 14a.

Given the stark contrast between what petitioners knew during the Class Period, and what they told the market, the Ninth Circuit correctly decided that the Complaint's allegations comprised the very sort of facts that would be material to Matrixx investors. App. 24a-26a.

Petitioners mischaracterize the lawsuit as one primarily involving so-called "adverse event reports" – a phrase they repeat 5 times in the Question Presented, and 12 more times in their Introduction alone. Petitioners' focus on the unique animals that are adverse-event reports allows them to bootstrap the caselaw discussing those specific reports with their attack on the panel's materiality holding. Yet official adverse-event reports may often be immaterial – compared to the pointed complaints about Zicam-induced anosmia that petitioners received. Under FDA regulations, an "adverse drug experience" is defined broadly to include "*[a]ny* adverse event associated with the use of a drug in humans, *whether or not con-*

sidered drug related." 21 C.F.R. §314.80(a) (emphasis added). Thus, a drug company will receive adverse-event reports "regardless of whether or not the illness had anything to do with" the company's product. *Carter Wallace II*, 220 F.3d at 41; *accord id.* ("Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill.").

In contrast to that randomness, however, the complaints made to petitioners here concerned a singular, dramatic reaction – the user's loss of sense of smell following Zicam's application into the nose – that complainants and medical researchers each attributed specifically to Zicam. The broad randomness of typical adverse-event reports is absent; these were specific, *identical* complaints brought to petitioners' attention. On those unique facts, the Ninth Circuit correctly ruled that reasonable investors would have wanted to know the undisclosed information before making the decision to buy Matrixx securities.

This Court's review is also unwarranted because the overall concept of "statistical significance" urged by petitioners is a poor proxy for Rule 10b-5 "materiality." While the latter concept concerns the importance a reasonable investor would affix to undisclosed or misstated information (*Basic*, 485 U.S. at 232), the former is "a technical term that concerns only whether an observed relationship is real or is the product of chance variation or the effect of an intervening variable." Melvin Aron Eisenberg, *Bad Arguments in Corporate Law*, 78 Geo. L.J. 1551, 1555 (1990). In other words, statistical significance "means that an observed difference cannot be attributed to chance alone, that something besides random error is afoot." Jack F. Williams, *Distrust: The Rhetoric and Reality of Means-Testing*, 7 Am. Bankr. Inst. L. Rev. 105, 131 n.105 (1999).

Notably, for purposes of a civil suit such as this, statistically significant differences "may or may not be *practically or legally significant.*" Williams, *supra*, 7 Am. Bankr. Inst. L. Rev. at 131 n.105 (emphasis in original); *see also* Richard Lempert, Symposium on Law and Economics: *Statistics in the Courtroom: Building on Rubinfeld*, 85 Colum. L. Rev. 1098, 1099 (1985) ("Statistical significance and substantive significance do not necessarily coincide; the likelihood of a statistically significant relationship varies both with sample size and the appropriateness of the statistical procedures."). The standard of proof in this civil action is a preponderance of the evidence, and "[w]hether a correlation between a cause and a group of effects is more likely than not – particularly in a legal sense – is a different question from that answered by tests of statistical significance, which often distinguish narrow differences in degree of probability."[8] Plainly, the requisite *materiality* of the undisclosed Zicam injuries known to petitioners need not necessarily coincide with the *statistical significance* of that same information – and the Ninth Circuit correctly recognized this.

Finally, this Court's review is unwarranted because the alleged anosmia reports linked to Zicam satisfy even the statistical-significance yardstick that the *Carter-Wallace* panels utilized.

Carter-Wallace was a securities-fraud action involving a pharmaceutical company and its epilepsy drug Felbatol. *Carter-Wallace II*, 220 F.3d 36; *In re Carter-Wallace, Inc.* ("*Carter-Wallace I*"), 150 F.3d 153 (2d Cir. 1998). Plaintiffs had alleged that the defendants' awareness of some 57 "adverse medical reports" concerning Felbatol users had triggered the company's duty to disclose those

[8] *Allen v. United States*, 588 F. Supp. 247, 417 (D. Utah 1984), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987).

reports to investors. *Carter-Wallace II*, 220 F.3d at 38. The Second Circuit disagreed, explaining that most of the 57 adverse reports were *unrelated to Felbatol use*, and thus not "statistically significant." *Id.* at 41. Only 6 of the 57 reports concerned "aplastic anemia," a frequently fatal form of acquired bone marrow failure. *Id.* at 38. "The other illnesses ... *were never linked* to Felbatol." *Id.* at 41 (emphasis added). Once defendants had received 4 additional reports of aplastic anemia linked to Felbatol, however, the number of adverse incidents – a total of 10 – *had* risen to what the panel deemed a statistically significant level. *Id.* at 40-42. It was on that date, held the Second Circuit, that "the linkage was established between aplastic anemia and Felbatol." *Id.* at 42.

Under that reasoning, the facts here satisfy even the significance benchmark that petitioners demand – for the Complaint tabulates at least 23 specifically linked Zicam-anosmia complaints – more than *double* the 10 adverse events deemed significant in *Carter-Wallace*. The math is straightforward: There were the ten anosmia cases detailed in the September 2003 Jafek-Linschoten-Murrow poster presentation, of course. App. 5a-6a. But there were also many others: The "cluster" of cases observed by Dr. Hirsch since 1999, with "at least one" described to Matrixx in December 1999 (ER68:¶25); the several patients Dr. Linschoten had treated for Zicam-linked anosmia, including one patient who had also complained to Matrixx (and whose complaint had prompted petitioner Clarot's September 2002 phone call to Dr. Linschoten) (ER68:¶26; App. 5a); the "other customers" whom Clarot conceded had been complaining to Matrixx "as early as 1999" (*id.*); and the nine plaintiffs in the four product liability lawsuits filed before and during the Class Period (ER68:¶49). Even under the most-conservative tabulation of these various injured consumers, the number of Zicam-anosmia complaints communicated to Matrixx

prior to and during the Class Period adds up to at least 23.[9]

That large number of undisclosed complaints, juxtaposed with petitioners' admission in their SEC filings that just one product-liability lawsuit against Matrixx could have crippling financial and reputational effects (App. 8a-9a), shows that the truth behind petitioners' omissions and misleading denials would have been highly material to Matrixx investors. Undoubtedly those investors also would have regarded as material the fact that petitioners claimed that Zicam's safey and efficacy had been established despite not knowing if that claim was accurate. The Ninth Circuit reached the correct result.

D. The Ninth Circuit's Scienter Holding Is Perfectly Consistent with This Court's *Tellabs* Standard

Almost as an afterthought, petitioners briefly address the Ninth Circuit's scienter holding. Pet. 16-17. They advance the fact-based argument that, under this Court's *Tellabs* decision, it is they who enjoy the more-compelling inference arising out of their nondisclosure of information relating to Zicam. Pet. 16. The supposed inference

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[9] Respondents have counted only the Dr. Jafek ten, Dr. Hirsch's one, Dr. Linschoten's/Clarot's one, the nine product-liability plaintiffs, and just two Zicam users from Clarot's admission of "other customers." The number of Zicam-anosmia reports known to petitioners increases if one credits the inferences that (a) Dr. Linschoten also told Clarot of her other, "several" patients suffering from Zicam-linked anosmia, and (b) the consumers complaining directly to Matrixx since 1999 totaled more than just two individuals. And, the numbers grow larger still if one accepts the equally compelling inference that at least some of the other *288* plaintiffs who eventually filed suit against Matrixx (ER68:¶49), or the *165* Zicam-anosmia patients evaluated by Doctors Jafek and Linschoten (ER68:¶30), also complained to Matrixx beforehand.

in petitioners' favor? That they did not disclose the information because "it was medically meaningless." *Id.*

This factual assertion neither comports with the record, nor credits the entirety of the Ninth Circuit's "holistic" scienter analysis. App. 32a.

Going through the record, the Ninth Circuit pointed out myriad facts supporting a strong inference of petitioners' scienter: By the time of petitioners' October 22, 2003 press release and conference call, petitioners were aware "of at least fourteen complaints regarding Zicam and anosmia." App. 29a. When petitioners spoke about the reputational and financial risks of product-liability claims in their November 2003 Form 10-Q "in the abstract," they gave no indication that the risk may have already come to fruition (App. 30a) – *i.e.*, the filing of the *Christensen* lawsuit. By the time of petitioners' February 2, 2004 press release disclaiming any possible link between Zicam and anosmia, in truth

> a strong inference can be drawn that [petitioners] knew that the statements alleging a link between Zicam and anosmia were not "completely unfounded and misleading." [Petitioners] allegedly knew about the presentation by Jafek to the American Rhinologic Society, Clarot's conversation with Linschoten, and several lawsuits alleging that Zicam caused anosmia.

App. 31a. In addition, petitioners' statements in that same press release that Zicam's safety had been "well established" by clinical trials conflicted with allegations that

> *Clarot told Linschoten* in September 2002 *that Matrixx had not conducted any studies* and asked her to participate in studies. The references in the press release to clinical trials establishing Zicam's safety also conflict with the March 4, 2004, news report that *Matrixx did not know* if Zicam could cause anosmia

> and [had] formed a medical advisory panel to conduct studies.

Id. (emphasis added). The court also rejected the district court's (mistaken) belief that respondents had to have shown petitioners' "motive" to raise a strong inference of their scienter. App. 28a; App. 32a ("'the absence of a motive allegation is not fatal'") (quoting *Tellabs*, 551 U.S. at 325). Viewing respondents' Complaint as a whole, the scienter inference raised was "'cogent and at least as compelling' as any 'plausible nonculpable explanation[]'" for petitioners' conduct. App. 33a (quoting *Tellabs*, 551 U.S. at 324).

In light of the foregoing fact-specific analysis, the Ninth Circuit's scienter holding was wholly consistent with this Court's admonition to consider a complaint's "allegations holistically." *Tellabs*, 551 U.S. at 326. It also was consonant with other circuits' similar reasoning concerning defendants' public statements in the face of undisclosed, contradictory information. *See, e.g., Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) (one of the "classic fact patterns" giving rise to a strong scienter inference is that defendants made certain statements "when they knew facts or had access to information suggesting that their public statements were materially inaccurate") (collecting cases); *Helwig v. Vencor, Inc.*, 251 F.3d 540, 552 (6th Cir. 2001) (en banc) (defendants' "disregard of the most current factual information" while making statements into the market is one of the "fixed constellations of facts that courts have found probative of securities fraud").

Petitioners' attempt to disparage the undisclosed information regarding Zicam's link with anosmia as "medically meaningless," and to defend the district court's elevation of "statistical significance" to the sole scienter inquiry, necessarily fail.

Given the unique facts presented, this Court's materiality and scienter precedents, and little evidence of an actual split of authority among the circuit courts, review is unwarranted.

III. CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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