No. 09-1156

IN THE
Supreme Court of the United States

MATRIXX INITIATIVES, *et al.*,
Petitioners,
v.

JAMES SIRACUSANO and NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the U.S. Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Respondents filed suit under § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5, alleging that petitioners committed securities fraud by failing to disclose "adverse event" reports – *i.e.*, reports by users of a drug that they experienced an adverse event after using the drug. The question presented is:

Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant.

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INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this and other federal courts in numerous cases related to the proper scope of the federal securities laws. *See, e.g., Morrison v. Nat'l Australia Bank Ltd*., 130 S. Ct. 2869 (2010); *Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc.,* 552 U.S. 148 (2008); *Tellabs, Inc. v. Makor Issue & Rights, Ltd.,* 551 U.S. 308 (2007).

As this Court has recognized, private securities fraud actions, "if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Tellabs*, 551 U.S. at 313. "As a check against abusive litigation by private parties," *id*., Congress adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), 109 Stat. 737, which among other things imposed exacting pleading requirements upon "any private action" arising from the Securities Exchange Act. *See* 15 U.S.C. § 78u-4(b). They included a requirement that the plaintiff "state with particularity facts giving rise to a strong inference" that the defendant acted with an intent to deceive, manipulate,

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief; letters of consent have been lodged with the clerk.

or defraud. 15 U.S.C. § 78u-4(b)(2)(A). WLF is concerned that the decision below, if allowed to stand, would effectively nullify the heightened pleading requirement with respect to scienter.

WLF is filing this brief to promote the interests of the business community and the public at large. It has no direct interest, financial or otherwise, in the outcome of this lawsuit. Because of its lack of direct interest, WLF believes that it can assist the Court by providing a perspective distinct from that of any party.

WLF's brief focuses exclusively on the scienter issue. Although WLF agrees with Petitioners that the complaint fails to meet the PSLRA's exacting pleading requirements with respect to materiality, WLF does not address that issue.

STATEMENT OF THE CASE

Petitioner Matrix Initiatives, Inc. is a corporation whose shares are publicly traded. Respondents are individuals who purchased Matrixx shares between October 22, 2003 and February 6, 2004. They filed suit against the corporation and several of its officers (collectively, Mattrix), alleging violations of §§ 10(b) and 20(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.*, and the Securities and Exchange Commission's Rule 10b-5, 17 C.F.R. § 240.10b-5. They allege that Matrixx materially misled investors by failing to alert them that its principal product, an over-the-counter cold medication marketed under the name Zicam Cold Remedy, caused some users to lose their sense of smell (a condition referred to as anosmia), and

that this emerging safety concern was likely to materially affect Matrixx's financial outlook. After reports of a Zicam-anosmia link were broadcast on ABC-TV's *Good Morning America* on February 6, 2004, the value of Matrixx shares dropped significantly.

On December 15, 2005, the district court granted Matrixx's motion to dismiss the complaint for failure to state a claim, with leave to amend. Pet. App. 35a-54a. The court focused solely on two of the required elements of a securities fraud claim: materiality and scienter. It determined that Respondents had inadequately alleged that any misleading omissions were "material" because Respondents "failed to present evidence of a *statistically significant* correlation between the use of Zicam and anosmia." *Id.* at 50a (emphasis added). It also determined that the complaint inadequately alleged scienter: the complaint failed to allege with particularity facts "giving rise to a strong inference that the defendant acted with the required state of mind with respect to each act or omission alleged to violate the securities law." *Id.* (citing 15 U.S.C. § 78u-4(b)(2)). The court noted that "the Complaint fail[ed] to allege any motive or state of mind with relation to the alleged omissions," and that "[t]here [were] no allegations Defendants disbelieved their statements as to the safety of Zicam, Defendants profited, or attempted to profit from public statements." *Id.* at 51a, 52a. Respondents chose not to amend and instead appealed the dismissal.

The Ninth Circuit reversed and remanded. *Id.* at 1a-34a. The court did not challenge the district court's determination that the complaint's factual allegations did not demonstrate a statistically significant relation-

ship between Zicam and anosmia, but it stated that "the district court erred in relying on the statistical significance standard to conclude that [Respondents] failed adequately to allege materiality." *Id.* at 23a. Rather, the district court should have undertaken "the fact-specific inquiry" into materiality that the appeals court understood to have been required by *Basic Inc. v. Levinson*, 485 U.S. 224 (1988). *Id.* at 24a. Citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the appeals court determined that the complaint included sufficient factual allegations – regarding "whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have considered significant," *id.* – to state a "plausible" claim for relief and to meet the PSLRA's standards for pleading materiality. *Id.* at 26a.

The appeals court also determined that the complaint's scienter allegations met the requirements of 15 U.S.C. § 78u-4(b)(2). *Id.* at 26a-35a. In determining the issue, the court reviewed not only allegations regarding the link between Zicam and anosmia but also statements made by Matrixx during the class period. *Id.* The court held that "[w]ithholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is 'an extreme departure from the standards of ordinary care' and 'presents a danger of misleading buyers and sellers.'" *Id.* at 34a (citing *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999)). The court concluded that "the inference that [Matrixx] withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently."

Id. at 35a. The decision included no discussion, however, regarding what it thought those "innocent[]" explanations might be, and no analysis regarding the comparative strengths of the competing inferences.

SUMMARY OF ARGUMENT

The PSLRA significantly heightened the requirement for pleading scienter in a securities fraud action. The complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). *Tellabs* explained that allegations cannot be said to give rise to the requisite "strong inference" unless they demonstrate that the inference that the defendant acted with scienter is "at least as compelling as any opposing inference one could draw from the alleged facts." 551 U.S. at 324. Yet, the Ninth Circuit determined that Respondents met the "strong inference" requirement without engaging in any analysis of competing inferences.

Had it done so, it would have recognized the existence of a far stronger, non-culpable inference: Mattrix decided not to release information regarding anosmia because it considered the information non-material in the absence of evidence suggesting a causal link between use of Zicam and anosmia. Moreover, the appeals court largely misconstrued the factual allegations upon which it relied in determining that the complaint raised a strong inference of scienter.

ARGUMENT

I. IN FINDING THAT THE COMPLAINT ADEQUATELY ALLEGED SCIENTER, THE APPEALS COURT FAILED TO APPLY THE PSLRA'S HEIGHTENED PLEADING REQUIREMENTS

In adopting the PSLRA in 1995, Congress imposed significantly heightened pleading requirements in securities fraud actions brought pursuant to § 10(b) and Rule 10b-5.[2] Under the PSLRA, any private securities complaint alleging that the defendant made a false or misleading statement or omission of "material fact" must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A).

Congress enacted the PSLRA "[A]s a check against abusive litigation by private parties." *Tellabs*, 551 U.S. at 313. Congress recognized that "[p]rivate

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[2] Even before adoption of the PSLRA, securities fraud cases had been subject to the heightened pleading requirements of Fed.R.Civ.P. 9(b), which requires, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

securities fraud actions, . . . if not adequately controlled, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Id.* *See* H.R. Rep. No. 104-369, at 31 (1995) (Conf. Rep.) (evidence of abuse included "routine filing of lawsuits . . . whenever there is a significant change in an issuer's stock price, without regard to any underlying culpability of [the defendants]," and "abuse of the discovery process to impose costs so burdensome that it is often economical for the victimized [defendants] to settle"). As acknowledged by the Court, "Proponents of the [PSLRA] argued that these abuses resulted in extortionate settlements, chilled any discussion of issuers' future prospects, and deterred qualified individuals from serving on boards of directors." *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006).

The "required state of mind" that must be pleaded in any securities fraud action is that the defendants intended "to deceive, manipulate, or defraud" the purchasers or sellers of the security. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 (1976). This requirement to plead scienter is inherently more demanding than the pleading requirement with respect to materiality. It is quite plausible that someone who makes a materially false statement or omission did so without any intent to deceive. The Court has explicitly rejected the argument that "facts that tend to show a materially false or misleading statement (or material omission) are ordinarily sufficient to show scienter as well." *Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1797 (2010). The Court explained:

> We recognize that certain statements are such that, to show them false is normally to show scienter as well. It is unlikely, for example, that someone would falsely say "I am not married" without being aware of the fact that his statement is false. Where § 10(b) is at issue, however, the relation of factual falsity and state of mind is more context specific. An incorrect prediction about a firm's future earnings, by itself, does not automatically tell us whether the speaker deliberately lied or just made an innocent (and therefore nonactionable) error.

Id. at 1797-98. Similarly, when a pharmaceutical company fails to disclose adverse information reports (reports that later are determined to be material to the company's future earnings), the fact of materiality by itself tells us little about whether the company intended to deceive investors. *See City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1260 (3d Cir. 2001) ("[A]llegations that the defendant possessed knowledge of facts that are later determined to have been material, without more, is not sufficient to demonstrate that the defendant intentionally withheld those facts from, or recklessly disregarded the importance of those facts to, a company's shareholders in order to deceive, manipulate, or defraud.").

Petitioners have convincingly demonstrated that the appeals court erred when it ruled that the complaint adequately pleaded materiality. But even if one accepts the materiality ruling, it does not follow that the complaint also adequately pleaded scienter. WLF respectfully submits that the complaint comes nowhere

close to meeting to rigorous scienter pleading standard imposed by 15 U.S.C. § 78u-4(b)(2)(A).

A. As Interpreted by *Tellabs*, § 4(b)(2)(A) Requires Courts to Examine All Plausible Inferences Regarding The Defendant's Mental State

The Court had occasion in *Tellabs* to construe the PSLRA's heightened pleading standards regarding scienter. The Court observed that § 78u-4(b)(2)(A)'s "strong inference" language "unequivocally raised the bar for pleading scienter." *Tellabs*, 551 U.S. at 321. It held that "Congress required plaintiffs to plead with particularity facts that give rise to a 'strong' – *i.e.*, a powerful or cogent – inference" of scienter. *Id.* at 323.

Moreover, the Court explained:

> The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. . . . [T]he inference of scienter must be more then merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations.

Id. at 323-24. The Court held that a complaint cannot survive a Rule 12(b)(6) motion to dismiss for failure to state a claim unless "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

While absence of allegations regarding the defendants' motives for intentionally deceiving investors "is not fatal," the Court stated that motive can be a relevant consideration in determining whether the inference of scienter is sufficiently strong. *Id.* at 325. The Court added that "omissions and ambiguities" in the complaint "count against inferring scienter" because the PSLRA imposes on the plaintiff an obligation to plead "with particularity" facts sufficient to give rise to the requisite "strong inference." *Id.* at 326.

B. Contrary to *Tellabs*, the Appeals Court Engaged in No Consideration of Competing Inferences

In determining that the complaint did not satisfy the PSLRA pleading requirements, the district court engaged in the comparative analysis mandated by *Tellabs*. For example, the district court considered the competing inferences that arguably arose from Matrixx's September 2003 decision not to permit Dr. Bruce Jafek to use the Zicam and Mattrix names in connection with a medical presentation, and concluded as follows:

> Plaintiffs argue that Defendants' actions in informing Dr. Jafek that the University of

> Colorado did not have permission to use Zicam marks is evidence of scienter. However, the argument is not well taken. It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability. Furthermore, in the letter from an Allied Waste researcher informing Dr. Jafek he did not have permission to use Zicam marks, Mr. Clarot [one of the Petitioners] stated "we are very much interested in learning more about adverse reports included in your presentation and, to the extent you have valid clinical data supporting your conclusions, we would appreciate receiving that immediately."

Pet. App. 51a.

In contrast, the Ninth Circuit engaged in no such comparative analysis of competing inferences regarding scienter. It mentioned the denial of permission to Dr. Jafek as a factual allegation that contributed to the inference of scienter, *id*. at 32a, but it did not discuss whether "innocent" inferences could be drawn from the same factual allegation.

Indeed, the Ninth Circuit utterly failed to engaged in *any* comparative analysis of competing inferences regarding scienter. Instead, it merely recited allegations from the Consolidated Amended Complaint (CAC) that it deemed supportive of an inference of scienter, *id*. at 28a-33a, and then concluded its analysis with the following *ipse dixit*:

> Viewing the CAC as a whole, the inference of

> scienter is "cogent and at least as compelling" as any "plausible nonculpable explanation[ ]" for Appellees' conduct. *Tellabs*, 551 U.S. at 324. Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is "an extreme departure from the standards of ordinary care" and "presents a danger of misleading buyers and sellers." *Silicon Graphics*, 183 F. 3d at 976. We therefore conclude that the inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently.

Pet. App. 33a-34a.

In the absence of any indication that it complied with *Tellabs*'s requirements that it "must consider any plausible, nonculpable explanations for the defendant's conduct" and then consider whether those explanations are more cogent than an inference that Matrixx acted with scienter, the Ninth Circuit did not begin to comply with *Tellabs*'s mandate. Indeed, as noted above, the Ninth Circuit did not even make reference to the nonculpable explanation (accepted by the district court) for Matrixx's response to Dr. Jafek's September 2003 request to use the Matrixx and Zicam names.

Congress adopted the PSLRA to prevent securities fraud cases from proceeding past the pleadings stage in the absence of strong evidence that the defendants intended to deceive investors. That

congressional purpose would come to naught if the PSLRA's heightened scienter pleading requirement could be deemed satisfied without any meaningful effort being made to determine whether opposing inferences are more cogent than the inference of scienter.

II. THE MOST COGENT INFERENCE FROM THE FACTS ALLEGED IS THAT MATRIXX WITHHELD INFORMATION BECAUSE IT DID NOT CONSIDER THE INFORMATION TO BE MATERIAL

At all stages of this litigation, the focus of Respondents' claim has been Mattrix's failure to disclose information regarding an alleged link between Zicam and anosmia. Thus, the district court dismissed the complaint because it determined that the complaint failed to assert factual allegations demonstrating "a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publically disclose complaints and the University of Colorado study a material omission." Pet. App. 50a. Similarly, the appeals court viewed the claim as one alleging a "fail[ure] to disclose material information regarding Zicam." *Id.* at 3a. After citing nine allegations in the complaint that went "to the question of whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have considered significant," *id.* at 24a-25a, the appeals court concluded that the complaint "sufficiently alleged materiality" under the PSLRA pleading standards. *Id.* at 26a. The question on which this Court granted review is, "Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC

Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant."[3] Thus, although the complaint alleges that Mattrix affirmatively made a number of materially false or misleading statements during the class period, the case has proceeded for the past five years on the basis of Matrixx's failure to disclose information about the alleged Zicam-anosmia link, not on the basis of the false statements. Respondents have limited themselves to arguing that the statements in question were false or misleading due solely to Matrixx's failure to include therein information regarding the alleged Zicam-anosmia link.

In the portion of its opinion that addresses scienter, the Ninth Circuit nonetheless includes a lengthy discussion of the allegedly false statements uttered by Mattrix. Pet. App. 28a-34a. That discussion is wholly appropriate when addressing scienter, even though the alleged falsity and materiality of those statements has never been a focus of this lawsuit. As *Tellabs* explained, "The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." 551 U.S. at 322-23. The Ninth Circuit undertook its examination of each of the allegedly false statements – including the February 2 and 6, 2004 Matrixx press releases – in recognition of its obligation

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[3] *See also* Respondents Opp. Br. at 16 ("[T]he Ninth Circuit's decision concerned the materiality of information that petitioners failed to disclose to investors.").

"to conduct a holistic review" of the entire complaint for purposes of determining whether the factual allegations of the complaint were sufficient to satisfy the PSLRA's scienter requirement. Pet. App. 27a.

The conclusion reached by the Ninth Circuit – that the statements made by Matrixx strengthen the inference that Matrixx acted with scienter – is not well taken. In particular, Ninth Circuit has misconstrued a number of those statements.

More importantly, regardless whether some of the complaint's factual allegations support an inference that Mattrix intended to deceive investors, that inference is not nearly as strong as a competing inference: that Mattrix decided not to release information regarding anosmia because it considered the information non-material in the absence of evidence suggesting a causal link between use of Zicam and anosmia.

A. Matrixx Had Reason to Believe that Information Regarding Anosmia Was Non-Material in the Absence of Evidence Suggesting Statistical Significance

The case has proceeded in the lower courts on the assumption that the complaint does not allege facts suggesting a statistically significant association between the use of Zicam and the onset of anosmia.[4] The district

[4] As Petitioners' brief explains, a link between use of a product and a health event is deemed to be "statistically significant" if the probability is less than 5% that any observed association is

court determined that the 12-to-23 anosmia complaints that Matrixx received before the end of the class period (from among the millions of Zicam uses) were not statistically significant, and held that evidence of failure to disclose non-statistically significant adverse events did not meet § 78u-4(b)(1)'s pleading standard for materiality. Pet. App. 50a. The court offered Respondents an opportunity to amend their pleadings in order to allege statistical significance, *id.* at 53a-54a, but they declined the offer. The appeals court did not challenge the district court's finding regarding statistical significance. It held, however, that factual allegations establishing statistical significance are not required by § 78u-4(b)(1). *Id.* at 23a-24a. Rather, the appeals court held, it is sufficient to allege facts "regarding the possible link between Zicam and anosmia" that a "reasonable investor would have considered significant." *Id* at 24a.

Because the Ninth Circuit held that allegations demonstrating statistical significance were not required by the PSLRA, its determination that Respondents adequately stated a cause of action necessarily assumed the possibility that the complaint did not include such allegations. Accordingly, the scienter issue must be addressed based on the assumption that the anosmia reports received by Matrixx during the class period were not statistically significant.[5] Under those circum-

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actually the result of random error. Courts routinely rely on statistical significance to distinguish between random occurrences and associations that could be causal. *See* Pet. Br. 34-42.

[5] Moreover, to the extent that there is any doubt regarding whether the complaint adequately alleges statistical significance,

stances, the most cogent inference to be drawn from the complaint's allegations is that Matrixx decided not to disclose the anosmia reports because it believed in good faith that the securities laws did not require the disclosure of adverse event reports that were not statistically significant.

Pre-2004 federal appellate court decisions were unanimous in concluding that securities fraud plaintiffs suing a pharmaceutical company for failing to disclose adverse event reports could satisfy neither the PSLRA nor the Rule 9(b) pleading standards for materiality and scienter unless they alleged facts demonstrating a statistically significant association between use of the company's drug and the reported condition. *See, e.g., Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000); *In re: Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36, 41 (2d Cir. 2000); *In re: Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998) ("Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by – rather than randomly associated with – use of the drugs and are sufficiently serious and frequent to affect future earnings."). Given the state of the law during the 2003-04 class period, a pharmaceutical company in Matrixx's shoes almost surely would have believed that it was not required to disclose adverse event reports that were not statistically significant. By far the most cogent inference regarding

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the doubt must be resolved in Matrixx's favor. *Tellabs* held that any "omissions and ambiguities" in a complaint "count against inferring scienter." 551 U.S. 326.

Matrixx's state of mind, therefore, is that Matrixx decided not to disclose the adverse event reports because it believed that disclosure was neither required nor appropriate, not because it sought to deceive investors.

The Court's ultimate disposition of the materiality issue will not affect disposition of the scienter issue because it will not affect the inferences that may properly be drawn from Matrixx's decision not to disclose the anosmia complaints received from Zicam users. Thus, even if the Court determines that Respondents' complaint meets the PSLRA's materiality pleading requirement despite the failure to allege statistical significance, that determination would have been unknowable in 2003-04 and thus would shed no light on Matrixx's thought processes at the time.

Moreover, Petitioner has pointed out numerous other reasons why Mattrix had good reason to believe that the 2003-04 anosmia complaints were not statistically significant.[6] In particular, the existence of an adverse event report suggests nothing by itself

[6] Indeed, although FDA concluded in 2009 that the alleged association between Zicam and anosmia raised legitimate safety concerns, that issue is far from settled. In its most recent 10-K report filed with the SEC, Matrixx asserted, "[W]e disagree strongly with the FDA's allegations that Zicam Cold Remedy nasal gel products may be unsafe. . . . The Company's position is supported by the cumulative science, a multi-disciplinary panel of scientists, and the decisions of 10 separate federal judges in 10 different cases in multiple jurisdictions." Matrixx Initiatives Inc., Form 10-K (Annual Report) (filed June 7, 2010 for the period ending March 31, 2010) at 14.

regarding causation.[7] Zicam users occasionally experience adverse medical conditions, but so do many people who do not use Zicam. Pet. Br. at 46. Matrixx had especially good reason to be wary of claims that Zicam caused anosmia, because (as Respondents concede) the common cold is a leading factor affecting sense of smell and thus "the population most likely to use cold remedy products is already at increased risk of developing anosmia." Complaint ¶38, J.A. 78a. Accordingly, Matrixx would have had little basis for concluding that the small number of reported anosmia cases were being caused by use of Zicam rather than by the medical condition for which the Zicam was being taken.

The Ninth Circuit cited to "existing studies linking zinc sulfate to the loss of smell." Pet. App. 5a. But Zicam has never contained zinc sulfate. Its active ingredient is zinc gluconate, a different compound. Matrixx would have had good reason to doubt the relevance – to the Zicam safety issue – of polio studios from the 1930s regarding the effects of zinc sulfate.

In sum, the allegations of the complaint underscore that Matrixx had good reason to believe that the anosmia reports were not statistically significant and thus not "material." Under those circumstances, the most cogent inference – regardless whether the reports are ultimately deemed "material" – is that

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[7] Moreover, even if there is a true association between two factors, there may be no causal relationship. For example, just because gray hair is associated with death rate does not mean that gray hair causes death.

Matrixx decided not to disclose the reports because it deemed disclosure neither required nor appropriate, not because it wished to deceive investors.

B. Matrixx's November 2003 SEC Filing Does Not Support an Inference of Scienter

On October 14, 2003, the first product liability suit – alleging damage to sense of smell caused by use of Zicam – was filed against Matrixx. On November 12, 2003, Matrixx filed a Form 10-Q with the SEC for the third quarter of 2003. The Form 10-Q made no reference to the October 14 lawsuit. The Ninth Circuit concluded that the omission created an inference of scienter because "[w]ithholding reports of . . . lawsuits concerning the product responsible for the company's remarkable sales increase is an extreme departure from the standards of ordinary care and presents a danger of misleading buyer or sellers." Pet. App. 33a.

The appeals court's finding is without merit. Far from constituting "an extreme departure from the standards of ordinary care," Matrixx's decision not to reference the lawsuit in the 10-Q report fully complied with SEC regulations. The duty to disclose lawsuits in SEC filings is governed by the SEC's Regulation S-K, 17 C.F.R. § 229.103. SEC guidance provides that "[a] legal proceeding need only be reported in the 10-Q filed for the quarter in which it became a reportable event." SEC Release No. 5949, *Amendments to Disclosure Forms and Regulations* (July 28, 1978), 1978 WL 170913, *27. The Matrixx 10-Q at issue covered the quarter ending September 30, 2003, two weeks before

the filing of the first product liability suit. Thus, the lawsuit was not reportable until the next quarterly 10-Q; and that next 10-Q did, in fact, disclose the October 14 lawsuit. Moreover, Regulation S-K provides that pending litigation generally need not be disclosed in a 10-Q unless the claim for damages exceeds 10% of the company's current assets. *See* 17 C.F.R. § 229.103, Instruction 2. Damages sought in the October 14 lawsuit constituted but a minuscule fraction of Matrixx's current assets, far less than 10%. Indeed, Respondents have never alleged that Matrixx violated Regulation S-K by failing to report legal proceedings.

Compliance with Regulation S-K does not absolutely preclude a finding, in subsequent securities fraud litigation, that information about a lawsuit was material and thus should have been disclosed (whether in an SEC filing or elsewhere). *City of Philadelphia v. Fleming Cos.,* 264 F.3d at 1267. Nonetheless, courts generally accept SEC determinations with respect to reporting obligations to be "persuasive authority" regarding materiality determinations. *Id.* at 1266-67. *See also, Basic Inc. v. Levinson,* 485 U.S. 224, 239 n.16 (1988) ("The SEC's insights are helpful, and we accord them due deference."). In light of Mattrix's compliance with SEC disclosure requirements, the appeals court's determination that nondisclosure represented "an extreme departure from the standards of ordinary care" is simply implausible. Nothing about the non-disclosure creates any inference that Matrixx *intended* to deceive investors.

The appeals court stated that the inference of scienter arose in part because the November 12, 2003,

Form 10-Q included boilerplate language regarding the risks of product liability litigation. Pet. App. 30a. The court faulted Matrixx for discussing those risks while giving "no indication that the risk may already have come to fruition." *Id.* The court analogized the situation to *Berson v. Applied Signal Tech., Inc.,* 527 F.3d 982 (9th Cir. 2008), in which a company was faulted for boasting (in one of its SEC filings) that it had a significant amount of backlogged work, without disclosing that some of the backlogged work had actually been stopped and was "at serious risk of being cancelled altogether." *Id.* at 29a-30a. The Ninth Circuit thought that the 10-Q might mislead some investors because, "[s]imilar to *Berson*," it spoke of the risk of product liability claims "in the abstract" without mentioning that one lawsuit had already been filed. *Id.* at 30a. The analogy to *Berson* is wholly inapt, and the criticism of Matrixx makes no sense. The boilerplate language in the Form 10-Q could not possibly have misled investors because it said nothing to suggest that no product liability lawsuits had been filed, and (unlike the SEC filing in *Berson*) it made no boasts that placed Matrixx in a more favorable light. Moreover, there is no plausible basis for inferring that Matrixx included the boilerplate language (while omitting any mention of the October 12 lawsuit) for the purpose of deceiving investors.

C. Matrixx's Decision to Investigate All Complaints Thoroughly Before Deciding How To Proceed Does Not Support an Inference of Scienter

Based largely on Matrixx's failure to disclose

immediately every report it received regarding anosmia, the Ninth Circuit inferred that Matrixx intended to deceive investors regarding its financial prospects. WLF respectfully submits, to the contrary, that Matrixx's course of conduct was much more consistent with that of a pharmaceutical company acting proactively and prudently to discover the nature of the association (if any) between Zicam and anosmia before issuing any statements on the topic.

For example, it was Petitioner Timothy Clarot, Matrixx's Vice President for Research and Development, who first reached out to Dr. Miriam Linschoten in September 2002 to learn more about her treatment of a patient suffering from anosmia. Complaint ¶26, J.A. 68a. Clarot was aware of the treatment because the patient had contacted Matrixx directly. *Id.* Far from seeking to suppress Dr. Linschoten's information, Clarot sought information about her patient, stated that Matrixx had hired a consultant to review Zicam, and requested that she send him information about studies that linked zinc *sulfate* to loss of smell. *Id*. at 68a-69a. After he received the information about those studies, he called Linschoten again to request her participation in animal studies that Matrixx planned to conduct regarding the effects of Zicam. Complaint ¶27, J.A. 69a.

The Ninth Circuit faulted Matrixx for denying Dr. Jafek permission to use the names "Matrixx" and "Zicam" in his September 2003 poster presentation to the American Rhinologic Society. Pet. App. 32a. The appeals court concluded that this refusal supported an inference that Matrixx intended to deceive investors. *Id.* But as noted above, the district court rejected that

inference, concluding, "It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability." *Id.* at 51a. The appeals court never considered that alternative, nonculpable inference. Nor did Matrixx's actions lead to the suppression of any medical data: Dr. Jafek still alerted other doctors to his suspicions regarding a causal link between zinc gluconate and anosmia, and other doctors who were interested in his findings would have had no difficulty determining which over-the-counter medications contained zinc gluconate.

Moreover, the very letter to Dr. Jafek upon which the Ninth Circuit relied also evidenced Mattrix's eagerness to learn more about any link between Zicam and anosmia. J.A. 117a-119a. The letter stated that Matrixx had conducted two double-blind randomized clinical trials of zinc gluconate, and there were no reports of anosmia in either study. *Id.* The letter nonetheless added:

> [W]e are very much interested in learning more about the adverse reports included in your presentation and, to the extent you have clinical data supporting your conclusions, we would appreciate receiving that immediately.

Id. at 117a-118a.

The complaint contains no allegation that Dr. Jafek supplied the requested information, or that he ever conducted a clinical study regarding the alleged Zicam-anosmia link. Nonetheless, as the complaint concedes, in response to Dr. Jafek's poster presentation

Matrixx convened a two-day meeting of physicians and scientists "to review current information on smell disorders." Complaint ¶ 45, J.A. 82a.

The absence of any personal financial motive for deceiving investors also supports an inference that Matrixx was delaying disclosure for the purpose of investigating the alleged Zicam-anosmia link more fully. The Ninth Circuit conceded that Respondents had not alleged that Matrixx or its executives had "engaged in unusual or suspicious stock sales at the same time that they were attempting to downplay the reports of anosmia," Pet. App. 32a, but then cited *Tellabs* for the proposition that while "motive can be a relevant consideration," the "absence of a motive allegation is not fatal" to a securities fraud claim." *Id.* (quoting *Tellabs*, 551 U.S. at 324). But while the absence of financial motivation may not *preclude* a finding that Matrixx acted with scienter, it was certainly a highly relevant consideration. Accordingly, the Ninth Circuit erred in failing to draw therefrom an inference of nonculpable intent and comparing the cogency of that inference to the inference that Matrixx intended to deceive investors.

Finally, the Ninth Circuit inaccurately stated that the two-day meeting of physicians and scientists was convened in February 2004 in response to the information disclosed in the February 6, 2004 *Good Morning America* broadcast. Pet. App. 33a. In fact, that meeting had been in the works for months and, as conceded in the complaint, was organized in response to Dr. Jafek's September 2003 poster presentation. Complaint ¶ 45, J.A. 82a.

In sum, the most cogent inference regarding Matrixx's state of mind is that it delayed releasing information regarding anosmia complaints in order to provide itself an opportunity to carefully review all evidence regarding any link between Zicam and anosmia. Courts have recognized that a delay-reporting-while-conducting-studies rationale is a prudent course of action and negates an inference that the manufacturer of a drug or medical device intended to deceive investors. *See, e.g., In re Medtronic Inc. Securities Litigation*, 618 F. Supp. 2d 1016, 1036 (D. Minn. 2009).

D. Matrixx's February 2 and 6, 2004 Press Releases Do Not Support an Inference of Scienter

In response to press reports linking Zicam to anosmia, Matrixx issued largely identical press releases on February 2, 2004, and February 6, 2004, denying a causal link between Zicam and anosmia. The Ninth Circuit concluded that the press releases contained materially false information and thus that their issuance strengthened the inference of scienter. Pet. App. 30a, 31, 33a.

The Ninth Circuit's conclusion is based on a mischaracterization of the press releases. The principal paragraph in both press releases read as follows:

> 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). 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 trails. In fact, in neither study were there any reports of anosmia related to the use of the compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

J.A. 193a-194a, 201a-202a. The complaint contains no allegations suggesting that any of the preceding statements are inaccurate.

The Ninth Circuit faulted the press releases for failing to "say whether Mattrix studied the intranasal use of zinc gluconate for safety, as opposed to efficacy." Pet. App. 31a. That is not a fair criticism of the press releases, which neither stated nor implied that the two studies were explicitly designed to determine whether there was a causal connection between use of Zicam and anosmia or any other medical condition. Rather, a fair reading of the releases indicates that Mattrix's safety claims were based on: (1) the absence from the clinical trials of "any reports of anosmia related to the use of" zinc gluconate; and (2) the absence of any meaningful difference in "[t]he overall incidence of adverse events" between those treated with Zicam and those treated with a placebo. That evidence was more than sufficient for Matrixx to claim truthfully that the "safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established."

The Ninth Circuit also concluded that the inference of scienter was strengthened by alleged inconsistencies between the press releases and a later statement (contained in a February 19, 2004 Form 8-K filing with the SEC) that Matrixx had determined that "there was insufficient evidence to determine whether zinc gluconate affected the sense of smell." Pet. App. 33a. It also stated that "Mattrix allegedly subsequently admitted that 'they don't know if their nasal gel could cause loss of smell.'" *Id.* at 22a n.6 (quoting from a March 4, 2004 news story, which apparently was based on the Form 8-K filing).

The appeals court has mischaracterized the Form 8-K. Matrixx did not state that company management had determined that it did not know "if their nasal gel could cause loss of smell." The press releases accurately stated that all available clinical evidence indicated that Zicam did not cause anosmia. The Form 8-K did not contradict that statement. Rather, it stated that a panel of doctors and scientists convened by Matrixx had determined, in the days following issuance of the press releases, that more evidence was needed because "there was insufficient evidence to determine whether zinc gluconate affected the sense of smell." Matrixx management responded to that determination in a wholly appropriate manner: it filed a Form 8-K with the SEC and initiated a study focusing on whether there existed a causal relationship between use of Zicam and anosmia.

The Ninth Circuit said that the February 2 press release was inaccurate because by that date "a strong inference can be drawn that [Matrixx] knew that the

statements alleging a link between Zicam and anosmia were not 'completely unfounded and misleading.'" Pet. App. 31a. That sentence mischaracterizes the press release. The press release termed "completely unfounded and misleading" claims that Zicam products "cause" anosmia, not (as the Ninth Circuit phrased it) claims alleging "a link" between Zicam and anosmia. J.A. 193a.

Finally, the Ninth Circuit faulted the February 2 press release for labeling as "completely unfounded and misleading" a January 30, 2004 Dow Jones report "that the FDA was investigating Zicam and anosmia." Pet. App. 32a-33a. The appeals court once again mischaracterized the press release. Matrixx did not deny that FDA was investigating Zicam; rather, it stated that it was "not aware of an FDA inquiry." J.A. 193a. Indeed, the complaint itself does not allege that FDA was conducting an investigation in January 2004, and even now there is nothing in the record to indicate that an FDA investigation was taking place.

In sum, the February 2 and 6, 2004 press releases were accurate, and nothing in either document supports the Ninth Circuit's conclusion that issuance of those documents supports an inference of scienter.

CONCLUSION

Amici curiae request that the Court reverse the decision of the court of appeals.

Respectfully submitted,

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