No. 09-

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 a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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MT/2SO

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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 First, Second, and Third Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the Ninth Circuit below rejected a statistical significance standard and allowed the case to proceed despite the lack of any allegation that the undisclosed adverse event reports were statistically significant. 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.

PARTIES TO THE PROCEEDING

Petitioners are Matrixx Initiatives, Inc., Carl Johnson, William Hemelt, and Timothy Clarot, defendants-appellees below.

Respondents are James Siracusano, named plaintiff and appellant below, and the NECA-IBEW Pension Fund, lead plaintiff and appellant below, on behalf of themselves and all others similarly situated who purchased securities of Matrixx between October 22, 2003 and February 6, 2004.

RULE 29.6 DISCLOSURE

Matrixx Initiatives, Inc. has no parent corporation and no person or publicly-traded corporation owns more than 10% of Matrixx's stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals is reported at 585 F.3d 1167 and is reprinted in the Appendix to the Petition ("App.") at 1a-34a. The district court's opinion is available at 2005 WL 3970117 and is reprinted at App. 35a-54a.

JURISDICTION

The court of appeals issued its decision on October 28, 2009, and denied a petition for rehearing and rehearing *en banc* on December 23, 2009. App. 55a-56a. The Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTES AND REGULATION INVOLVED

The relevant statutory provisions of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. §§ 78u-4(b)(2), and Securities and Exchange Commission (SEC) Rule 10b-5 are reproduced in the appendix. App. 57a-58a.

INTRODUCTION

This case presents a question of recurring importance under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 on which the courts of appeals are squarely divided: whether drug companies have a duty to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an ad-

verse event after using the drug—where the reports do not reflect statistically significant evidence that the adverse event may be caused by use of the drug. Three Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the court below rejected a statistical significance standard and allowed the case to proceed based on the failure to disclose adverse event reports that are not statistically significant.

That decision has immense consequences for pharmaceutical companies, investors, and consumers. The Food and Drug Administration receives hundreds of thousands of adverse event reports each year. Those reports are made without regard to whether there is any established relationship between use of a drug and an adverse event. Under the court of appeals' ruling, a pharmaceutical company that fails to disclose a small number of such complaints would be subject to suit under § 10(b) even though the complaints are not statistically significant and therefore do not indicate any causal relationship between use of the drug and the adverse event.

Faced with that rule, the only safe course for a company would be to provide investors with every adverse event report even though the company has no reason to believe that the report casts the slightest doubt on the safety of the drug. That result is not only harmful to reasonable investors, who depend on receiving significant rather than useless in-

formation. It is also detrimental to consumers. If drug companies disclose every adverse event report, the unfortunate result may be to deter confused consumers from using drugs that would be beneficial to their health.

As three courts of appeals have correctly concluded, a statistical significance standard is necessary to prevent these untoward consequences. The Court should therefore grant certiorari to resolve the conflict in the circuits on this issue and hold that adverse event reports can form the basis for a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 only when they are statistically significant.

STATEMENT OF THE CASE

1. Petitioner Matrixx Initiatives, Inc. is a pharmaceutical company that sells cold remedy products through its wholly-owned subsidiary, Zicam, LLC. App. 2a. One of Matrixx's main products is Zicam Cold Remedy (Zicam), which was produced in the form of a nasal spray or gel. Zicam's active ingredient is zinc gluconate. *See* App. 2a-3a, 4a.

On April 27, 2004, respondents brought suit on behalf of a putative class of investors who purchased Matrixx stock between October 22, 2003 and February 6, 2004. App. 4a. Respondents alleged that Matrixx and three of its executives (petitioners) violated § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 by failing to disclose material information regarding Zicam Cold Remedy. Specifically, respondents alleged that use of Zicam could cause "anosmia," or loss of the sense of smell. App. 3a.

In support of their conclusory allegation of a causal connection between Zicam and anosmia, respondents relied on allegations that, in a four-year period between 1999 and 2004, Matrixx received approximately 12 reports of user anosmia: one from Dr. Alan Hirsch, another from Dr. Miriam Linschoten, and ten from Dr. Bruce Jafek. *See* App. 25a. Respondents also alleged that, in the class period, Matrixx was named in four Zicam-related lawsuits, involving a total of nine plaintiffs, and in their briefing, respondents counted those plaintiffs as additional complainants. App. 25a-26a. It is not clear whether those plaintiffs actually represent additional adverse events.[1] Ultimately, however, the precise number of adverse event reports is beside the point. The critical point, for present purposes, is that respondents did not allege in their complaint that the small number of adverse event reports in the class period was statistically significant, much less allege facts that would raise an inference of statistical significance.

2. Petitioners filed a motion to dismiss respondents' complaint for failure to state a claim. The district court granted the motion. App. 35a-54a. The court invoked the Second Circuit's decision in *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000), as the standard for determining when allegations of undisclosed adverse event reports can satisfy the materiality requirement under § 10(b) and Rule 10b-5. As the district court ex-

[1] Respondents' complaint did not allege that the plaintiffs in the Zicam-related lawsuits were additional complainants, rather than simply a subset of the 12 individuals whose adverse events had already been reported to Matrixx.

plained, in *Carter-Wallace*, the Second Circuit held that no claim can be based on the nondisclosure of adverse event reports "unless such reports provide reliable statistically significant information that a drug is unsafe." App. 45a. Applying that standard, the district court concluded that respondents had alleged "no data as to the reliability and accuracy of the user complaints," and that "[e]ven if there were data as to the reliability" of the complaints, "12 user complaints is not statistically significant." App. 50a. The court therefore concluded that respondents failed to allege that the nondisclosure of the reports was a "material omission." *Id.*

The district court noted that the complaint alleged that by April 2004, after the class period had ended, there were 165 adverse event reports. App. 53a. It therefore allowed respondents to replead to cure the deficiency in the Complaint. But it warned that "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class period* that was sufficiently serious and frequent to affect future earnings, any amendment would be futile." App. 54a (internal quotation marks omitted). The district court thereby used the statistical significance standard as a measure of both materiality and scienter.

3. The court of appeals reversed. The court recognized that "the [district] court relied on the statistical significance standard used by the Second Circuit in *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1999), and *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000)." App. 23a. The court of appeals

"conclude[d], however, that the district court erred in relying on the statistical significance standard" to rule on materiality. *Id.* According to the court, "reliance on the statistical significance standard is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

The court then held that the respondents "sufficiently pled materiality" based on the nondisclosure of the adverse event reports, even though the reports were not alleged to be statistically significant. App. 34a. And based on the number and nature of the reports, the court further held that the inference that petitioners withheld the reports "intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation." *Id.*[2]

REASONS FOR GRANTING THE PETITION

THE COURT SHOULD GRANT REVIEW TO DECIDE WHETHER A PLAINTIFF CAN STATE A CLAIM UNDER § 10(B) AND RULE 10B-5 BASED ON NONDISCLOSURE OF ADVERSE EVENT REPORTS THAT ARE NOT STATISTICALLY SIGNFICANT

The courts of appeals are divided on 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 failure to disclose adverse

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[2] While the appeal was pending in the Ninth Circuit, the FDA issued a warning letter, stating that some of the Zicam products "may pose a serious risk to consumers." App. 3a n.1. Because that warning letter was written more than five years after the close of the class period, it has no bearing on the question presented here.

event reports that are not statistically significant. That issue is an important and recurring one, not only for pharmaceutical companies and investors, but also for consumers who rely on the products those companies produce. This case presents an ideal vehicle for resolving that issue. And the court of appeals answered the question presented incorrectly. A plaintiff should be permitted to pursue a claim under § 10(b) based on nondisclosure of adverse event complaints only when those complaints are statistically significant. The Court should grant certiorari and reverse the judgment below.

A. The Courts of Appeals Are Divided on the Question Presented

The courts of appeals are divided on the question presented in this case. The First, Second, and Third Circuits have adopted a statistical significance standard for claims based on nondisclosure of adverse event reports, while the Ninth Circuit in this case expressly rejected a statistical significance standard.

1. a. *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153 (2d Cir. 1998) (*Carter-Wallace I*), is the seminal decision adopting the statistical significance standard. In an opinion by Judge Winter, the Second Circuit held that a drug company's failure to disclose adverse event reports could "not be[] materially misleading until [the company] had information that [the drug] had caused a statistically significant number of" adverse events. *Id.* at 157. The court explained that "[d]rug 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." *Id.*

In *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000) (*Carter-Wallace II*), the Second Circuit reaffirmed that a claim under § 10(b) cannot be based on failure to disclose adverse event reports that are not statistically significant. In that case, the court of appeals explained that because adverse event reports to the FDA encompass any adverse event associated with a drug, "whether or not considered drug related," and because "[s]ome adverse events may be expected to occur randomly," such reports are not indicative of a "causal relationship" until they are "statistically significant." 220 F.3d at 41 (emphasis omitted). The court further held that nondisclosure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." *Id.* Nor did it matter to the court that, after the class period ended, the drug was eventually linked to a series of deaths. The court explained that reports could not "relate back" in time and "reflect on Carter-Wallace's reasonable belief that the reports were random." *Id.* at 41. The Second Circuit continues to follow the statistical significance rule. *See Avon Pension Fund v. Glaxosmithkline PLC*, 343 F. App'x 671, 672-73 (2d Cir. 2009); *Masters v. Glaxosmithkline*, 271 F. App'x 46, 50 (2d Cir. 2008).

The Third Circuit has also adopted the statistical significance standard. In an opinion by then-Judge Alito, the Third Circuit held that "'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 ef-

fects may be caused by—rather than randomly associated with—use of the drugs.'" *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157). Because the reports at issue were not "statistically significant," the court held that their nondisclosure was not "materially misleading." *Id.*

Similarly, the First Circuit has adopted the statistical significance test. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1st Cir. 2008), the First Circuit rejected a plaintiff's § 10(b) claim that was based on nondisclosure of adverse event reports. The court explained that there was "no basis to conclude that these results . . . were statistically significant," and that "'the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.'" *Id.* at 50, 53 (quoting *Carter-Wallace II*, 220 F.3d at 41) (emphasis omitted).

b. In conflict with the decisions of those three circuits, the court of appeals in this case squarely rejected "the statistical significance standard used by the Second Circuit in *In re Carter-Wallace*." App. 23a. The court explained that, in its view, "the district court's reliance on the statistical significance standard to conclude that [respondents] failed to establish materiality [was] inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

2. As a result of the Ninth Circuit's rejection of the statistical significance standard, the pleading

requirements for stating a securities claim against a pharmaceutical company depend entirely on the jurisdiction in which a plaintiff chooses to bring suit. Companies defending suits in the First, Second, and Third Circuits will be able to obtain prompt dismissals of claims based on adverse event reports lacking statistical significance. Companies forced to defend securities fraud suits in the Ninth Circuit, however, will be required to proceed past the pleadings stage, with all the costs and pressure to settle unmeritorious suits that entails. That difference in treatment of similarly situated companies is intolerable.

The conflict in the circuits is particularly alarming given the class-action nature of most § 10(b) actions. Any plaintiff who can establish jurisdiction in a district court within the Ninth Circuit could prevent application of the statistical significance standard to a nationwide class of investors. In effect, the Ninth Circuit's rule gives any class action plaintiff who can secure jurisdiction within the Ninth Circuit's wide geographic region a ready weapon to blunt the protection against unmeritorious suits offered by the First, Second, and Third Circuits. This Court should grant certiorari to resolve the conflict in the circuits and prevent the Ninth Circuit's rule from effectively becoming the law of the land without review by this Court.

B. The Question Presented Is a Recurring Issue of National Importance, and This Case Presents an Ideal Vehicle for Resolving That Issue

1. The question presented is a frequently recurring issue of national importance, deserving of a uni-

form national resolution. In 2008 alone, the FDA received a total of 526,527 adverse event reports for drugs and therapeutic biologic products. *See* U.S. Food and Drug Administration, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. Under the court of appeals' approach, a small number of such reports, if undisclosed, could potentially form the basis for a lawsuit under § 10(b).

Plaintiffs are particularly likely to target the instances in which the FDA issues a warning letter or a recall. *See N.J. Carpenters*, 537 F.3d at 47. In fiscal year 2008, for example, the FDA's Center for Drug Evaluation and Research—the body responsible for regulating over-the-counter and prescription drugs—issued 379 product recalls and 87 warning letters. *See* U.S. Food and Drug Administration, *The Enforcement Story* 10-9, 10-16 (2009), http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf. Under the court of appeals' standard, once such a letter or recall is issued, plaintiffs would have every incentive to sue based on nondisclosure of adverse event reports made at an earlier time, even if there were no statistically significant evidence of a causal link between the drug and the effect at that time. *See*, *e.g.*, *Carter-Wallace I*, 150 F.3d at 157 (no claim where adverse reports received before company acted were not statistically significant).

The effects of the Ninth Circuit's rejection of the statistical significance standard are profoundly un-

settling. The court's decision dramatically expands the number of investor suits against pharmaceutical companies that state a claim and substantially increases the pressure on companies to settle meritless claims.

The Court has previously granted review in similar circumstances. In *Dura Pharmaceuticals, Inc. v. Broudo*, the Court rejected a Ninth Circuit rule that "permit[ted] a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence." 544 U.S. 336, 347 (2005) (internal quotation marks omitted); *see In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995) (Posner, C.J.) (recognizing the "intense pressure to settle" if a class is certified). The court of appeals' decision in this case has the same effect, forcing defendants to undergo discovery and the risk of class certification for claims that have no basis in medical reality.

To avoid these intolerable effects, a company's only safe alternative would be to provide investors with every adverse event report even though it has no reason to believe that the report casts the slightest doubt on the safety of the drug and even though it has no material significance to a reasonable investor. As the Court has recognized before, providing investors with such information "is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976).

Disclosing every adverse event report would also be detrimental to consumers. Because such information, no matter how carefully phrased, is likely to spawn confusion, the unfortunate effect would be to deter consumers from purchasing drugs that are needed to improve their health.

The resolution of the question presented in this case is therefore of great importance to pharmaceutical companies, investors, and consumers. For that reason, review of that question is clearly warranted.

2. This case also presents an ideal vehicle for resolving the question presented. In a four-year period in which Matrixx made countless sales of Zicam, respondents were able to identify 12 adverse event reports. Respondents did not allege in their complaint that the reports were statistically significant, nor did they allege facts that would support a plausible inference of statistical significance.

Application of the statistical significance standard therefore would result in dismissal of the complaint. Indeed, applying the statistical significance standard, the district court did precisely that. And while the court of appeals reversed that dismissal, it did so only because it rejected the statistical significance standard. This case therefore squarely presents the question whether a plaintiff can state a § 10(b) claim based on nondisclosure of adverse event reports that are not statistically significant.

C. The Court of Appeals Erred in Rejecting the Statistical Significance Standard

1. The Ninth Circuit erred in rejecting the statistical significance standard adopted by the First, Sec-

ond, and Third Circuits. This Court held in *Basic* that information is not material under the securities laws unless there is "'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus.,* 426 U.S. at 449). "The role of the materiality requirement" is to "filter out essentially useless information that a reasonable investor would not consider significant." *Id.* It is not to bury investors in an "avalanche of trivial information." *TSC Indus.*, 426 U.S. at 448.

The statistical significance standard properly implements that materiality requirement. When adverse event reports are not statistically significant, they fail to provide any indication that the effects "may be caused by . . . use of the drugs." *Carter-Wallace I*, 150 F.3d at 157. Instead, they indicate no more than a random relationship between use of the drug and the effect. *Id.* Accordingly, as the courts that have adopted the statistical significance standard have concluded, such reports are not material: they would not be viewed by reasonable investor as "significantly altering the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32.

2. The Ninth Circuit rejected the statistical significance requirement because it believed that any "bright-line rule" for materiality is inconsistent with *Basic*. App. 34a But the Court in *Basic* rejected the bright-line rule proposed in that case because it was based on policy considerations that were not tied to "the significance of the information upon the investor's decision." 485 U.S. at 234. The statistical sig-

nificance standard, by contrast, is directly tied to the significance of adverse event reports to a reasonable investor. As noted above, the statistical significance standard captures the common sense insight that no reasonable investor would be likely to deem important reports of adverse events that are not statistically significant.

In *Jackvony v. RIHT Financial Corp.*, 873 F.2d 411, 415 (1st Cir. 1989), the First Circuit, in a post-*Basic* case, similarly adopted a bright-line rule that was directly tied to the importance of the information to a reasonable investor. In an opinion by then-Judge Breyer, the First Circuit held that internal discussion regarding a merger feeler from another company that precedes any merger negotiations is categorically non-material. The court explained that "[a]ny reasonably sophisticated investor in securities buying shares in a large corporation would expect that, from time to time, other corporations might express an interest in buying, or that the large corporation's directors might discuss what it should do if it obtains such offers." *Id.* The court added that "[f]or large corporations to make public announcements every time directors discuss any such matter in terms as vague as those presented in this evidence or receive 'tentative feelers' of the general sort revealed by th[e] evidence [before the court] . . . would more likely confuse, than inform, the marketplace." *Id.*

The same kind of analysis applies here. Any reasonably sophisticated investor buying shares in a pharmaceutical company must realize that consumers will, from time to time, experience adverse events after using the company's product. *Carter-*

Wallace II, 220 F.3d at 41. "Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill." *Id.* Consequently, until adverse reports suggest "the ill effects may be caused by—rather than randomly associated with—use of the drug[]," no reasonable investor would likely deem that information material. *Carter-Wallace I*, 150 F.3d at 157. Requiring disclosure of every adverse report, as the court of appeals effectively did below, "would more likely confuse, than inform, the marketplace." *Jackvony*, 873 F.2d at 415. The court of appeals therefore erred in rejecting the statistical significance standard.

3. In addition, application of a statistical significance requirement is necessary to comport with the PSLRA's requirement that plaintiffs "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). This Court in *Tellabs* held that, "[t]o qualify as 'strong' within the intendment of § 21D(b)(2) . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

Where adverse event reports are not statistically significant, the inference of fraudulent intent is not "at least as compelling as any opposing inference of nonfraudulent intent." *Id.* Instead, the more compelling inference is that defendants did not disclose information that was not statistically significant because it was medically meaningless. Thus, as the Second Circuit held in *Carter-Wallace II*, nondisclo-

sure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." 220 F.3d at 41. For that reason as well, the court of appeals erred in rejecting the statistical significance standard. To resolve the conflict in the circuits on this issue of recurring importance and to correct the error by the court below, this Court's review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 23, 2010

APPENDIX

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APPENDIX A

COURT OF APPEALS OPINION

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JAMES SIRACUSANO, Individually and on behalf of all others similarly situated,

Plaintiff-Appellant,

NECA-IBEW PENSION FUND,

Claimant-Appellant,

v.

MATRIXX INITIATIVES, INC.; Carl J. Johnson; William J. Hemelt,

Defendants-Appellees.

No. 06-15677

D.C. Nos.
CV 04-0886 MHM
CV 04-1012 MHM

OPINION

Appeal from the United States District Court
for the District of Arizona
Mary H. Murguia, District Judge, Presiding

Argued and Submitted
June 9, 2009—San Francisco, California

Filed October 28, 2009

Before: Mary M. Schroeder, A. Wallace Tashima and Carlos T. Bea, Circuit Judges.

Opinion by Judge Tashima

COUNSEL

Joseph D. Daley, Coughlin Stoia Geller Rudman & Robbins LLP, San Diego, California, for the plaintiff-appellant.

Michael G. Yoder, O'Melveny & Myers LLP, Newport Beach, California, for the defendants-appellees.

OPINION

TASHIMA, Circuit Judge:

Matrixx Initiatives, Inc. ("Matrixx") is a pharmaceutical company that sells cold products through its wholly-owned subsidiary, Zicam, LLC. One of its main products is Zicam Cold Remedy, which comes in several different forms.[1] Plaintiffs-

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[1] On June 16, 2009, the Food and Drug Administration

Appellants are lead plaintiff, NECA-IBEW Pension Fund, and named plaintiff, James Siracusano, in a class action brought against Matrixx and three Matrixx executives (collectively "Appellees") under the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Appellants alleged that Appellees violated the Securities Exchange Act of 1934 by failing to disclose material information regarding Zicam Cold Remedy — specifically, that Zicam causes a condition called anosmia, which is a loss of the sense of smell, in its users. The district court granted in part and denied in part Appellees' motion to strike portions of the complaint and granted Appellees' motion to dismiss the complaint and the action. We have jurisdiction pursuant to 28 U.S.C. § 1291. We reverse and remand for further proceedings.

("FDA") issued a warning letter to Matrixx, setting forth the FDA's conclusion that several Zicam Cold Remedy products "may pose a serious risk to consumers who use them." http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm (visited July 19, 2009; information moved to http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm166931.htm). The FDA stated that it 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.*

BACKGROUND[2]

On April 27, 2004, Appellants filed a class action against Matrixx and three individual defendants — Carl Johnson, Matrixx's Chief Executive Officer, President and a director; William Hemelt, Matrixx's Chief Financial Officer and Executive Vice President; and Timothy Clarot, Matrixx's Vice President and Director of Research and Development — on behalf of investors who purchased Matrixx securities during the class period, October 22, 2003, to February 6, 2004. Zicam Cold Remedy accounted for approximately 70 percent of Zicam's sales during the class period. Zicam Cold Remedy's active ingredient is zinc gluconate and can be applied as a nasal spray or a gel. Appellants alleged that Appellees were aware that numerous users of Zicam had developed anosmia, but that they failed to disclose the risk and instead issued false and misleading statements regarding Zicam.

I. Allegations of Adverse Information Regarding Zicam

In December 1999, Dr. Alan Hirsch, the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., "called Matrixx's customer service line to inquire into the

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[2] The following allegations are taken from the Consolidated Amended Complaint ("CAC"). In reviewing the district court's dismissal for failure to state a claim, we accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). As such, the allegations are hereafter stated as fact.

amount of zinc contained in Zicam nasal gel." CAC ¶ 25. Hirsch spoke with a Mr. Landau and explained that at least one of Hirsch's patients had developed anosmia after using Zicam. Hirsch stated that other studies had indicated potential problems with "intranasal application of zinc," and offered to conduct a clinical study on the issue. Mr. Landau declined his offer.

In September 2002, Clarot, Vice President of Research and Development, called Miriam Linschoten, Ph.D., of the University of Colorado Health Sciences Center. Clarot contacted Linschoten because a patient Linschoten had treated for loss of smell following use of Zicam also had complained to Matrixx. Linschoten expressed concern that Zicam, an over-the-counter product, contained no warning that it could cause a loss of smell. Clarot told Linschoten that Matrixx had received similar complaints from other customers as early as 1999. Linschoten asked whether Matrixx had performed any studies, told Clarot about existing studies linking zinc sulfate to the loss of smell, and offered to send Clarot information regarding those studies. Clarot replied that Matrixx had not done any studies but that "it had hired a consultant to review the product." CAC ¶ 26.

On September 20, 2002, Linschoten sent an email to Clarot including abstracts on the link between zinc sulfate and the loss of smell. Clarot called Linschoten to ask if she would participate in animal studies to be conducted by Matrixx, but Linschoten declined because she focused on human, not animal, research.

Linschoten, Dr. Bruce Jafek of the University of

Colorado School of Medicine, and another colleague planned to submit their findings regarding ten patients who had developed anosmia following Zicam use in a presentation to the American Rhinologic Society on September 20, 2003. On September 12, 2003, "Matrixx sent a letter to Jafek stating that he did not have permission to use Matrixx's name or the names of its products" in the presentation. CAC ¶ 29. Jafek asked for permission to use the Zicam name, but Matrixx refused. The presentation to the American Rhinologic Society accordingly was made without naming Zicam. "Jafek's findings regarding Zicam were ultimately disclosed to the public on February 6, 2004 on *Good Morning America*." *Id*.

"As of April of 2004, Dr. Jafek had evaluated over 100 cases of anosmia following Zicam use." CAC ¶ 30. Linschoten had treated approximately 65 such patients, all of whom complained of "an 'immediate, severe burning' immediately following use of Zicam nasal gel, followed by a loss of smell." None of the patients had fully recovered. *Id*. Jafek and Hirsch "have observed that the Zicam nasal spray does reach the upper area of the nasal cavity where smell reception occurs."

II. Allegations of Misleading Statements

On October 22, 2003, Matrixx issued a press release announcing that its net sales for the third quarter of 2003 had increased by 163% over the third quarter of 2002. Johnson was quoted in the press release as follows:

> The Zicam brand is poised for growth in the upcoming cough and cold season with improved retail exposure by virtue of three [new] unique oral delivery forms of our Zicam

> Cold Remedy product, the resumption of our television advertising campaigns in recent weeks and the momentum from last year's successful season. Additionally, our retail partners have come to rely on the Zicam brand not only as an efficacious product for their customers, but also for the profitability that Zicam branded products produce for their respective bottom-lines.

Matrixx 10/22/2003 press release. Appellants alleged that these statements were materially false and misleading because they failed to disclose Appellees' awareness of the material health risk that Zicam posed to consumers.

On October 23, 2003, Appellees held an earnings conference call, at which Johnson expressed his "enthusiasm for the most recently completed quarter" and his "optimis[m] about the future." 10/23/03 Tr. at 1. Johnson explained that

> we have very strong momentum going into the upcoming cough and cold season. In addition, what lies behind these results is a unique product in the Zicam product line, a product that offers a unique benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms, and tremendous support that we are receiving from our retail customers.

Id. at 2. Johnson further expressed the expectation for the year that "our revenues will be up in excess of 50% and that earnings per share for the full year will be in the 25-30¢ range." Id. at 5. Hemelt stated that the growth "was driven by increased sales of all

10 of our Zicam products," explaining that approximately one-third of the increase in sales was due to "three new Zicam oral cold remedy products," and that the remainder of the increase "was due to increased sales of our other seven Zicam products." *Id.* at 4. Johnson and Hemelt then answered questions.

At one point, they were asked to "make any comment on the litigation MTXX or its officers are involved in, or whether or not there is any SEC [Securities and Exchange Commission] investigation." *Id.* at 17. They replied that "[t]he officers of this company are not involved in any litigation," and that they were not aware of any SEC investigation.[3] *Id.* at 17-18. Johnson concluded by reiterating "the optimism we have for the future." *Id.* at 32. There was no mention of the anosmia issue.

On November 12, 2003, Matrixx filed its Form 10-Q report for the third quarter of 2003 with the SEC. The section of the Form 10-Q that Appellants alleged was false and misleading was this paragraph from the section on Risk Factors:

> *We may incur significant costs resulting from product liability claims*
>
> We are subject to significant liability should

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[3] A lawsuit was filed against Matrixx and Zicam on October 14, 2003, in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia. Matrixx was served on October 23, 2003, the day of the earnings conference call. *Christensen v. Matrixx Initiatives, Inc.*, No. 03-cv-0146, Docket No. 3.

> use or consumption of our products cause injury, illness or death. Although we carry product liability insurance, there can be no assurance that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. 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.

CAC ¶ 35. Appellants alleged that these statements were materially false and misleading because Appellees "failed to disclose that a lawsuit alleging that Zicam caused anosmia had already been filed and, given the findings of the researchers at the University of Colorado it was highly likely that additional suits would be filed in the future." *Id.*

Matrixx issued a press release on January 7, 2004, in which it "upwardly revised its guidance for fiscal year 2003. The Company expects total 2003 revenues to grow by greater than 80 percent compared to 2002 and fully diluted earnings per share to be in the range of $0.33 to $0.38." CAC ¶ 37. Matrixx reported that "[t]he increase in the guidance for 2003 reflects a much greater incidence of colds than previously anticipated." *Id.*

On January 30, 2004, an article in the Dow Jones Newswires reported that the FDA was "looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives Inc. (MTXX) may be causing some users to lose their sense of smell." The article stated that "[t]he FDA's interest follows at least three lawsuits filed by individuals against Matrixx and Zicam LLC, a wholly-owned subsidiary, by users of Zicam Cold Remedy." Appellants alleged that Matrixx's stock declined after this report, "falling from $13.55 per share on January 30, 2004 to $11.97 per share on February 2, 2004." CAC ¶ 41.

On February 2, 2004, Matrixx issued a press release, "respond[ing] to the Dow Jones 'In The Money report: FDA Looks Into Complaints About Zicam,' by Carol S. Remond, alleging that the FDA is investigating consumer complaints regarding intranasal zinc gluconate-induced loss of smell." Matrixx 2/2/2004 press release. The press release stated:

> Matrixx Initiatives, Inc., the manufacturer of Zicam(R) Cold Remedy, is not aware of an FDA inquiry into the safety of our intranasal zincgluconate products . . . .
>
> All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.

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 trials. In fact, in neither study were there any reports of anosmia related to the use of this 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. A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.

The circumstances surrounding the development of Ms. Remond's column are extremely suspect. The article appeared online in public financial message boards almost immediately following its availability through the Dow Jones 'In The Money' subscription-only service. At least one of these message board postings was made by a registered user-name frequently used by Floyd Schneider, a defendant currently being

sued for defamation by Matrixx Initiatives. From at least August 2001 to the present, Schneider has posted false and defamatory statements about Matrixx on various Internet message boards using a variety of anonymous aliases. It has come to our attention that Schneider has also attempted to interfere with Matrixx' business by contacting our retail customers.

Ms. Remond's article appears on today's Dow Jones Newswire — the very day that Matrixx Initiatives is deposing Schneider. We believe that the timing of this article was manipulated by Schneider to interrupt the deposition process. We know that Ms. Remond and Schneider were in close communication during the development of Ms. Remond's article and even discussed the disclosure statement detailing the basis for our suit against Schneider, which has not yet been made public. Therefore, it is particularly troubling that Ms. Remond neglected to mention the defamation action or that Schneider was one of her chief sources of information. We consider her failure to mention these facts to be a significant omission in fair and balanced reporting.

Matrixx Initiatives would like to underscore that we intend to vigorously pursue those individuals involved in any effort to improperly discredit the company and its products. Furthermore, we strongly urge Dow Jones to open its own investigation to determine whether Dow Jones' credibility was undermined by the use of copyrighted

> material in an attempt to do further harm to the value and reputation of Matrixx Initiatives and its products.

Matrixx 2/2/2004 press release. Appellants alleged that Matrixx's "vigorous, but baseless, denials had their intended effect: the stock price rose, closing at $13.40 per share on February 3, 2004." CAC ¶ 41.

On February 6, 2004, the television show *Good Morning America* did a report on Matrixx's zinc gluconate products and anosmia. Reporter John Ferrugia reported that Jafek had treated "'more than a dozen patients'" and that four lawsuits had been filed, and others were "'being prepared.'" CAC ¶ 42. Appellants alleged that, "[i]n response to the *Good Morning America* segment . . . , the price of Matrixx common stock plummeted, falling from $13.05 per share on February 5, 2004, to close at $9.94 per share on February 6 — a one-day drop of 23.8% on unusually heavy trading volume." CAC ¶ 43.

On February 6, 2004, Matrixx issued another press release, describing the reports linking anosmia with zinc gluconate intranasal gels as "completely unfounded and misleading." Matrixx 2/6/2004 press release. Matrixx "assure[d] our consumers that Zicam Cold Remedy intranasal zinc gluconate products are manufactured and marketed according to Food and Drug Administration guidelines for homeopathic medicine." *Id*. Matrixx further asserted 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 trials. In fact, in neither study were there any reports of anosmia related to the use of this 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.
>
> A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. . . .
>
> A few researchers have attempted to link nasal products containing zinc to the onset of anosmia. However, this hypothesis is based on data from polio studies conducted in the 1930s using a concentrated zinc sulfate solution. Current nasal products, such as Zicam Cold Remedy, contain zinc gluconate, which is an entirely different compound.

Matrixx 2/6/2004 press release.

On February 19, 2004, Appellees filed a Form 8-K with the SEC, in which Matrixx stated that it had "convened a two-day meeting of physicians and scientists to review current information on smell disorders." CAC ¶ 45. The form stated that the meeting was in response to the September 20, 2003, presentation to the American Rhinologic Society.

The form further stated that, "[i]n the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

On March 4, 2004, Ferrugia, the reporter on the *Good Morning America* segment, reported on TheDenverChannel.com that Matrixx "now admit[ted] that they don't know if their nasal gel could cause loss of smell." CAC ¶ 47. The article stated that "[t]he stunning information came after a 7NEWS investigation found that some consumers who have used Zicam report the loss of smell." *Id*. The article reported that Matrixx initially "told us its studies showed the product [was] safe," but that it would begin studies to determine if the product could cause the loss of smell. *Id*. (alteration in original). The article further provided as follows:

> Doctors at the University of Colorado Taste and Smell Clinic have an increasing number of patients who say they lost their sense of smell after using Zicam intranasal gel, which contains zinc gluconate. Dr. Bruce Jafek has been documenting the cases from around the country, and there have been several lawsuits in at least five states. 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. In a filing to the Securities and Exchange Commission on issues affecting stockholders, Matrixx now discloses: "There is insufficient evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." What's more, after our initial investigation, dozens of consumers

> have filed complaints with the Food and Drug Administration. In response, the company formed a medical advisory panel in February. It says it will now conduct: ". . . animal and human studies to further characterize these post-marketing complaints." Study findings are expected to be available in 12 months. "It seems to me that those studies should have been done before they put the product on the market," said Jafek.

Id.

On March 19, 2004, Matrixx filed its Form 10-K with the SEC, stating that "numerous suits alleging that its Zicam product(s) caused anosmia had been filed." CAC ¶ 48. "As of December 31, 2003, suits involving three users of the Zicam® Cold Remedy nasal gel products had been filed in various federal and state courts." *Id*. Appellants stated that, "[a]ccording to Matrixx's own SEC filings, from late 2003 through October 2004 Matrixx has been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam caused damage to their sense of smell," and included in the complaint a table detailing the lawsuits. CAC ¶ 49. The table included suits filed on October 14, 2003, December 8, 2003, December 18, 2003, and January 23, 2004, as well as numerous suits following the close of the class period.

Appellants alleged that the financial information contained in Matrixx's Form 10-Q filed on November 12, 2003, was false and misleading and violated SEC rules and the Generally Accepted Accounting Principles ("GAAP") promulgated by the Financial Accounting Standards Board ("FASB"). Appellants

asserted that, at the time Matrixx filed the Form 10-Q,

> Matrixx should have disclosed, if not provided a reserve for, a potential contingency that had arisen related to safety issues concerning its products. During the Class Period, Matrixx did not disclose that several lawsuits had been filed against the Company, including one prior to the start of the Class Period, alleging that the Company's zinc gluconate-based products had caused plaintiffs to suffer from anosmia and that anecdotal evidence had surfaced questioning the safety of the Company's mainstay cold medication. The failure to disclose these known contingencies violated GAAP.

CAC ¶ 55. Appellants listed the FASB rules violated by Matrixx's Form 10-Q and asserted that "the undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, . . . is expected by investors . . . to be disclosed and is known by corporate officials . . . to be the type of information which is expected to be and must be disclosed." CAC ¶¶ 56-57.

Appellants alleged that, "[a]s a result of defendants' materially false and misleading statements and failure to disclose adverse information regarding Zicam, Matrixx securities traded at artificially inflated prices during the Class Period." CAC ¶ 58. Appellants also alleged that, "[d]uring the Class Period, defendants materially misled the investing public, thereby inflating the price of Matrixx common stock, by publicly issuing

false and misleading statements and omitting to disclose material adverse facts regarding Zicam, necessary to make defendants' statements, as set forth herein not false and misleading." CAC ¶ 59.

In the section of the complaint entitled "Additional Scienter Allegations," Appellants alleged as follows:

> [D]efendants acted with scienter in that defendants knew that the public statements or documents issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Matrixx, their control over, and/or receipt and/or modification of the Company's alleged materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Matrixx, participated in the fraudulent scheme alleged herein.
>
> Defendants were aware since at least September of 2003, that numerous users of their Zicam product had experienced a rare condition known as anosmia or loss of smell. Findings of post treatment anosmia were

> reported by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology at a medical conference in September of 2003. At the time, Dr. Jafek had reported 10 cases of anosmia after Zicam use. As of April of 2004, Dr. Jafek had evaluated over 100 such cases. On September 12, 2003, over one month before the start of the Class Period, Matrixx informed Dr. Jafek that "as a legal matter" he did "not have their permission to use their company name or product trademarks" in the poster reporting Dr. Jafek's research. In order to avoid threatened legal action from the Company, Dr. Jafek deleted any reference to Zicam or Matrixx from the poster which he used to present his research at a medical conference.[4]

CAC ¶¶ 63-64.

Appellees filed a motion to strike any allegations that concerned user complaints and lawsuits that occurred after the close of the class period. The district court denied the motion in part and granted it in part. The court reasoned that the relevant inquiry was not whether there was a link between Zicam and anosmia, but whether Appellees knew that their statements were false at the time they were made. The court therefore denied the motion to

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[4] We do not disturb the district court's order granting, in part, Appellees' motion to strike portions of the CAC related to research published after the close of the class period.

strike as to the complaints and lawsuits that were filed because those allegations were relevant to Appellees' knowledge of user complaints. However, the court granted the motion to strike as to Jafek's ultimate conclusions, which were published after the close of the class period.

The district court then dismissed the complaint without prejudice, reasoning, that the allegations of user complaints were not material because they were not statistically significant. The court also found that Appellants had failed sufficiently to allege scienter.

The court further stated that any amendment would be futile "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was 'sufficiently serious and frequent to affect future earnings.'" The court therefore granted the motion to dismiss and dismissed the complaint without prejudice. The court then entered judgment, dismissing the complaint and the action without prejudice.[5] Appellants timely appealed.

STANDARD OF REVIEW

The district court's dismissal for failure to state a

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[5] Although the judgment dismisses the action without prejudice, it is "final for purposes of [28 U.S.C.] § 1291 [because] it (1) is a full adjudication of the issues, and (2) clearly evidences the judge's intention that it be the court's final act in the matter." *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 845, 846 (9th Cir. 2009).

claim is reviewed de novo. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). We accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Id.* Dismissal is "inappropriate unless the plaintiffs' complaint fails to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

DISCUSSION

"Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), in combination with SEC Rule 1 0b-5, prohibits 'any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.'" *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1164 (9th Cir. 2009) (quoting 17 C.F.R. § 240.10b-5(c)). In order adequately to allege a violation of Rule 10b-5, "a plaintiff must [allege] '(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.'" *Id.* (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005)). The district court dismissed the complaint on the grounds that Appellants failed adequately to allege the first two elements; therefore, we address only those two elements.

I. Materiality

Appellants contend that Appellees' failure to disclose information regarding the possible link between Zicam and anosmia constituted the omission of a material fact. "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important

in deciding how to vote." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

"'Questions of materiality . . . involv[e] assessments peculiarly within the province of the trier of fact.'" *SEC v. Talbot*, 530 F.3d 1085, 1097 (9th Cir. 2008) (quoting *Arrington v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 651 F.2d 615, 619 (9th Cir. 1981)) (alterations in original). Thus, "the ultimate issue of materiality [is] appropriately resolved 'as a matter of law'" only where the omissions are "'so obviously important to an investor, that reasonable minds cannot differ on the question of materiality.'" *TSC*, 426 U.S. at 450 (quoting *Johns Hopkins Univ. v. Hutton*, 422 F.2d 1124, 1129 (4th Cir. 1970)).

The district court summarized the "allegations of links between Zicam and anosmia for which Defendants had knowledge" as follows: "a phone conversation between a Matrixx vice-president and University of Colorado researcher discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University of Colorado study citing 11 cases of anosmia in Zicam users."[6] District

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[6] The district court also reasoned that "Matrixx conducted a double-blind study regarding Zicam and not a single case of anosmia was reported." This was presumably a reference to Matrixx's February 2, 2004, press release, which states that "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." The press release, however, does not state that any tests established that the application of zinc gluconate to the nose is safe. In fact, as reported by Ferrugia on March 4,

Ct. Order at 11. The court then found that Appellants had failed adequately to allege materiality because the number of complaints of which Appellees were aware was not "statistically significant." The court relied on the statistical significance standard used by the Second Circuit in *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998), and *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000). We conclude, however, that the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality.

The Supreme Court has 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 and the significance of those inferences to him.'" *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988) (quoting TSC, 426 U.S. at 450) (second alteration in original). Instead, courts should engage in a "fact-specific inquiry" in assessing materiality. *Id.* at 240. Thus, "[d]etermining materiality in securities fraud cases 'should ordinarily be left to the trier of fact.'" *SEC v. Phan*, 500 F.3d 895, (9th Cir. 2007) (quoting

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2004, Matrixx allegedly subsequently admitted that "'they don't know if their nasal gel could cause loss of smell,'" and that they would "begin . . . testing to determine whether its zinc compound could be harmful when sprayed in the nose." Moreover, the complaint alleged that Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies.

In re Apple Computer Sec. Litig., 886 F.2d 1109, 1113 (9th Cir. 1989)); *see also No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 934-35 (9th Cir. 2003) (declining to adopt a bright-line rule to determine materiality, engaging in the fact-specific inquiry required by *Basic*, and finding that the plaintiffs had sufficiently pleaded materiality).

In relying on the statistical significance standard to determine materiality, the district court made a decision that should have been left to the trier of fact. Instead, we agree with the approach of the court in *In re Pfizer Inc. Securities Litigation*, 584 F. Supp. 2d 621 (S.D.N.Y. 2008), where the United States District Court for the Southern District of New York rejected the defendant pharmaceutical company's argument that the plaintiffs failed to plead materiality, which was based on the contention that three studies revealing adverse effects of the company's drug were not statistically significant. The court reasoned that it "cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact." *Id.* at 635-36.

Thus, we are to engage in the fact-specific inquiry required by *Basic*. In doing so, we must take the allegations in the complaint as true and construe them in the light most favorable to Appellants and determine whether the complaint "fails to state a claim to relief that is plausible on its face." *Zucco*, 552 F.3d at 989 (internal quotation marks omitted). The following allegations in the CAC go 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:

- In December 1999, Hirsch called Matrixx's customer service line and reported one patient who had developed anosmia after Zicam use and mentioned studies regarding intranasal application of zinc.
- In September 2002, Clarot called Linschoten because one of her patients had complained to Matrixx about Zicam and anosmia. Clarot told Linschoten that Matrixx had received similar complaints from other customers since 1999, and Linschoten told Clarot about studies linking zinc sulfate to loss of smell.
- On September 20, 2002, Linschoten sent Clarot an email with abstracts on the link between zinc sulfate and the loss of smell.
- In September 2003, Jafek presented findings about ten or eleven patients who suffered anosmia following Zicam use. Matrixx, through Clarot, stopped Jafek from using Matrixx's and Zicam's names in the presentation.
- On October 14, 2003, two plaintiffs filed suit against Matrixx in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia.
- On December 8, 2003, a plaintiff filed suit against Matrixx in Los Angeles Superior Court regarding Zicam and anosmia.
- On December 18, 2003, another suit regarding Zicam and anosmia was filed against Matrixx in Alabama state court and removed to federal court.

- On January 23, 2004, five plaintiffs filed a consolidated suit against Matrixx in the Superior Court of Maricopa County, Arizona regarding Zicam and anosmia. An additional 261 plaintiffs later joined this action, after the close of the class period.
- By April 2004, Jafek "had evaluated over 100 cases of anosmia following Zicam use," and Linschoten had seen 65 cases, although the time period of these allegations is not clear.

We believe that the foregoing allegations are sufficient to meet the pleading requirement under the PSLRA, which requires that:

> the complaint shall 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 or belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1). The allegations in the CAC are sufficient to meet that standard and, as well, to "nudge[ ] [Appellants'] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Appellants have sufficiently alleged materiality, and the district court's finding to the contrary is reversed.

II. Scienter

In order to plead scienter, the PSLRA requires the complaint to "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). The plaintiff "must allege that . . . the

defendant had an intention 'to deceive, manipulate, or defraud.'" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1065-66 (9th Cir. 2008) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976)). "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007). The complaint will survive a motion to dismiss "only if 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. This does not mean that a plaintiff must "plead more than she would be required to prove at trial." *Id.* at 311. Rather, "[a] plaintiff alleging fraud under § 10(b) action . . . must plead facts rendering an inference of scienter at least as *likely* as any plausible opposing inference." *Id.*

To establish scienter, "a complaint must 'allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness.'" *Zucco*, 552 F.3d at 991 (quoting *Daou*, 411 F.3d at 1015). We must first "determine whether any of the plaintiff 's allegations, standing alone, are sufficient to create a strong inference of scienter." *Id.* at 992. If not, we are to "conduct a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness." *Id.* Recklessness is defined as

> a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which

> presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.

In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 976 (9th Cir. 1999) (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990) (en banc)).

The district court here concluded that the CAC failed to allege the requisite scienter because it "fails to allege any motive or state of mind with relation to the alleged omissions." In order adequately to allege scienter, Appellants rely on their allegations that Appellees knew about the problems with Zicam but chose not to reveal them. Appellants also argue that the importance of Zicam to Matrixx's business supports the inference that Appellees intentionally withheld information of the link between Zicam and anosmia. Appellants also point to the revelations following the close of the class period that, contrary to their statements during the class period, Matrixx actually did not know if Zicam caused anosmia and decided to conduct studies after they had already vouched for the safety of Zicam.

Matrixx's first allegedly misleading statement was its October 22, 2003, press release, announcing the 163% net sales increase, attributed to Zicam, and stating that the Zicam brand was "poised for growth." The second statement was the conference call on October 23, 2003, again attributing the company's positive results to Zicam and projecting further growth. By the time of the press release and the conference call, Hirsch had called the customer service line regarding one patient, Clarot had spoken

with Linschoten regarding customer complaints, Jafek had presented his report of eleven patients, and the first lawsuit against Matrixx had been filed. Appellees accordingly were aware of at least fourteen complaints regarding Zicam and anosmia at the time they made these statements. In addition, Appellants alleged that Clarot told Linschoten in the September 2002 phone call that "Matrixx had received customer complaints of loss of smell as early as 1999." Appellants then alleged that the November 12, 2003, Form 10-Q was misleading because it spoke of the risk of product liability actions against the company without revealing that a lawsuit already had been filed.[7]

In *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982 (9th Cir. 2008), the defendants argued that a passage in the company's SEC filings regarding backlogged work alerted reasonable investors to the risk that the company might not get paid for work that had actually been stopped. We rejected the argument, stating that "[t]he passage . . . speaks entirely of as-yet unrealized risks and contingencies. Nothing alerts the reader that some of these risks may already have come to fruition, and that what the company refers to as backlog includes work that is substantially delayed and at serious risk of being cancelled altogether." Id. at 986. We therefore disagreed with the district court's finding that the statements were not misleading, reasoning that,

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[7] As Matrixx later admitted, up to and including the class period, Matrixx had conducted no studies on the safety of Zicam regarding any link to anosmia.

"once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of." *Id.* at 987; *cf. In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 208 (S.D.N.Y. 2008) ("By choosing to speak about the safety of [their drug], Defendants assumed a duty to disclose material information regarding adverse events."). After addressing scienter and loss causation, we reversed the district court's dismissal of the complaint. *Berson*, 527 F.3d at 987- 90.

Similar to *Berson*, the passage in the Form 10-Q speaks about the risks of product liability claims in the abstract, with no indication that the risk "may already have come to fruition." *Id.* at 986. At the time that Appellees filed the Form 10-Q, the CAC alleges facts sufficient for a jury to find that Clarot was aware of the potential anosmia problem. Moreover, the inference that high-level executives such as Johnson, Hemelt, and Clarot would know that the company was being sued in a product liability action is sufficiently strong to survive a motion to dismiss.

In response to the January 30, 2004, article in the Dow Jones Newswires that the FDA was investigating complaints of anosmia linked to Zicam, Matrixx issued a press release on February 2, 2004. By the time of this press release, three more lawsuits regarding anosmia had been filed against Matrixx. This press release cites the two double-blind studies regarding the "safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold," but, again, the press release did not say whether Matrixx studied the intranasal use of zinc gluconate for safety, as opposed to efficacy.

The press release also states that "statements alleging that intranasal Zicam products cause anosmia . . . are completely unfounded and misleading," and then devotes three paragraphs to discrediting the author of the article and urging Dow Jones to investigate the author.

By the time of the February 2, 2004 press release, a strong inference can be drawn that Appellees knew that the statements alleging a link between Zicam and anosmia were not "completely unfounded and misleading." Appellees 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. In addition, Matrixx's statements in the press release, that Zicam's safety was "well established" by their trials, conflict with the 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 formed a medical advisory panel to conduct studies.

Matrixx's February 6, 2004, press release, following the *Good Morning America* segment regarding Jafek's findings, repeated the statements that the safety of zinc gluconate to treat cold symptoms had been established in clinical trials, stated that the common cold affects the sense of smell, and stated that the studies linking zinc to anosmia were conducted in the 1930s using a different zinc compound. Matrixx 2/6/2004 press release.

Appellants have not alleged that Appellees engaged in unusual or suspicious stock sales at the same time that they were attempting to downplay the reports of anosmia. *See Silicon Graphics*, 183 F.3d at 986 (stating that "unusual or suspicious stock sales by corporate insiders may constitute circumstantial evidence of scienter") (internal quotation marks omitted). The Supreme Court has stated, however, that, "[w]hile it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, we agree with the Seventh Circuit that the absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 324.

On a holistic review of the CAC, the following picture is alleged. Matrixx received some customer complaints about Zicam and anosmia from 1999 to 2002. In 2002, Clarot was sufficiently concerned that he called Linschoten about one of her patients who had complained and then called to ask if she would participate in studies. In September 2003, Matrixx knew that Jafek and his colleagues were presenting findings about ten or eleven patients who developed anosmia after Zicam use and did not allow Jafek to use Matrixx's or Zicam's name in the presentation. In October 2003, Matrixx touted the potential for growth and profitability of Zicam in a press release and an earnings conference call. A lawsuit alleging anosmia in one Zicam user was filed in October 2003. In November 2003, Matrixx filed a Form 10-Q, but did not disclose the lawsuit in the section entitled "Risk Factors." More lawsuits were filed in December 2003 and January 2004.

On February 2, 2004, Matrixx issued a press release responding to the January 30, 2004, Dow

Jones report that the FDA was investigating Zicam and anosmia. This press release called the report "completely unfounded and misleading" and asserted that clinical trials had established the safety of zinc gluconate. On February 6, 2004, *Good Morning America* reported on the possible link between Zicam and anosmia, and Matrixx issued another press release asserting that zinc gluconate's safety was well established in clinical trials, even though it was subsequently reported that Matrixx had not conducted such studies. In a February 19, 2004, filing with the SEC, Matrixx stated that it had convened a panel of physicians and scientists to review the information and asserted that there was insufficient evidence to determine whether zinc gluconate affected the sense of smell. On March 4, 2004, a news article reported that Matrixx would begin studies to determine if Zicam caused anosmia.[8]

Viewing the CAC as a whole, the inference of scienter is "cogent and at least as compelling" as any "plausible non-culpable 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 or sellers." *Silicon*

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[8] We do not address Appellants' allegations that Appellees violated GAAP and FASB principles in the November 12, 2003, Form 10-Q. "Violations of GAAP standards can . . . provide evidence of scienter," but the violations must be described with sufficient particularity. *Daou*, 411 F.3d at 1016.

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.

CONCLUSION

The district court's reliance on the statistical significance standard to conclude that Appellants failed to establish materiality is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact. Viewing the CAC in the light most favorable to Appellants, we conclude that Appellants have sufficiently pled materiality to survive dismissal. Similarly, the inference that Appellees withheld the information regarding Zicam and anosmia intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation. For the foregoing reasons, the judgment of the district court is **REVERSED** and the case **REMANDED** for further proceedings consistent with this opinion.

REVERSED and REMANDED.

APPENDIX B

DISTRICT COURT OPINION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

James V. Siracusano, on Behalf of Himself, and All Other Similarly Situated, Plaintiff, vs. Matrixx Initiatives, Inc.; Carl J. Johnson; William J. Hemelt; and Timothy L. Clarot, Defendants.	No. CIV-04-0886-PHX-MHM No. CIV-04-1012-PHX-MHM **(consolidated)** **ORDER**

This is a securities fraud case brought pursuant to the Private Securities Litigation Reform Act of 1995 ("Reform Act"). Currently before the Court are Defendant's Motion to Strike, (Dkt. #72); and Defendants' Motion to dismiss. (Dkt. #73). After reviewing the motions and hearing oral argument on October 13, 2005, the Court issues the following Order.

I. Factual and Procedural Background

Defendant-Matrixx Initiatives Inc., ("Matrixx") develops and markets over-the-counter pharmaceuticals. Zicam, Matrixx's wholly-owned subsidiary, produces Zicam Cold Remedy. Between October 22, 2003 and February 6, 2004 ("Class Period"), Plaintiffs purchased thousands of Matrixx shares and instituted this class action on behalf of all purchasers during the Class Period. Am. Compl. ¶ 1. Plaintiffs allege that Matrixx and its officers violated the Securities and Exchange Act by issuing materially false and misleading statements concerning Zicam. Specifically, Plaintiffs assert Matrixx knew that Zicam may cause users to suffer a total and permanent loss of smell, known as anosmia. Further, Plaintiffs assert that while Matrixx warned investors that there was a potential for such lawsuits, Matrixx materially misled investors by not alerting them that such lawsuits had already been filed.

Plaintiffs allege in 1999 Dr. Alan Hirsh M.D., Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., recognized a link between Zicam use and anosmia and reported the possible link to Matrixx's customer service line and to a Mr. Landau, *Id.* at ¶ 25. In September 2002, Timothy L. Clarot, Matrixx's Vice President and Miriam R. Linchosten, Ph.D., of the University of Colorado, corresponded regarding a Zicam user complaining of anosmia and regarding studies linking zinc sulfate to anosmia. Id. at ¶¶ 26, 27. In September 2003, a collaborative research effort by medical researchers at the University of Colorado School of Medicine, Department of Otolaryngology, et al. ("University of Colorado

Study") identified 11 Zicam users who had suffered from anosmia. Am. Compl. ¶¶ 3, 24, 28. As of April 2004, Doctor Jafek had evaluated over 100 cases of anosmis and Dr. Linchosten estimated she had treated 65 users of Zicam who suffered from anosmia. *Id.*

Defendants did not disclose the University of Colorado study and instead informed Dr. Bruce Zafek, of the University of Colorado, that "as a legal matter [the University of Colorado] did not have [Matrixx's] permission to use their company name or product trademarks" in association with the University of Colorado study. *Id.* at ¶¶ 4, 29. Plaintiffs contend despite knowledge of the risk of anosmia, Defendants continued to make positive statements regarding Matrixx's growth and revenue and Zicam's safety. Specifically, on October 22, 2003, Matrixx issued a press release indicating net sales increased by 164% by the third quarter of 2002 and stating "[t]he Zicam brand is poised for growth in the upcoming cough and cold season" and the Zicam brand is relied on "as an efficacious product." *Id.* at 32. Again, on October 23, 2003 in a conference call with financial analyst, Defendant Johnson stated "we are extremely encouraged at this point . . . what lies beyond these results is a unique product in the Zicam product line. A product that offers a unique benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms." *Id.* at 33.

In a November 12, 2003 quarterly report, Defendants reiterated positive projections with a disclaimer "We may incur significant costs resulting from product liability claims." *Id.* At 35. On February 2, 2004, Plaintiff Matrixx issued a press

release stating:

> Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading. In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function. 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. In fact, in neither study were there any reports of anosmia related to the use of this compound

Id. at 38

On January 30, 2004 an article published in the *Dow Jones Wire* indicated three product liability suits related to the use of Zicam had been filed. *Id.* at ¶¶ 6, 40. On February 2, 2004, Matrixx representatives issued a press release stating that "statements alleging intranasal Zicam products cause anosmia are completely unfounded and misleading." *Id.* at ¶ 6 Additionally Matrixx stated "[i]n no clinical trial of intranasal zinc gluconate gel products [active ingredient in Zicam] has there been a single report of loss or diminished olfactory function." *Id.*

On February 6, 2004, *Good Morning America* reported the University of Colorado study demonstrated Zicam may cause users to suffer from anosmia, four product liability lawsuits related to Zicam users suffering from anosmia were pending, and similar lawsuits were expected. *Id.* at ¶¶ 8,42. The lawsuits were filed from October 2003 to

January 2004. *Id.* at 49. Also on February 6, 2004, Matrixx issued a press release entitled "Reaffirm[ing] safety of intranasal Zicam Cold Remedy" and reiterating that there had been no clinical trial of intranasal zinc gluconate gel causing anosmia. *Id.* at ¶ 9. On February 5, 2004, after the *Good Morning America* broadcast, the price of Matrixx common stock fell 23.8%. *Id.* at ¶¶ 8,43. After meeting with physicians, on February 19, 2004, Defendants filed a Form 8-K with the Security Exchange Commission ("SEC") stating "[i]n the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc glutonate, when used as recommended, affects a person's ability to smell." *Id.* at ¶ 46.

Also, during the Class Period, Plaintiffs allege Defendants falsely reported Matrixx's profits for the third quarter of 2003 in violation of Generally Accepted Accounting Principals ("GAAP"). Specifically, Plaintiffs contend Defendants failed to disclose that several product liability lawsuits had been filed against Matrixx, which were known contingencies and should have been disclosed. *Id.* ¶¶ 50-57.

Defendants move to dismiss Plaintiffs' first amended complaint on the grounds that plaintiffs have failed to state a claim for relief under Rule 12(b)(6), Federal Rules of Civil Procedure, and have failed to plead with particularity as required by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (Reform Act), 15 U.S.C. § 78u-4.

II. Motion to Strike

A. Legal Standard

Fed. R. Civ. P. 12(f) provides that a party may bring a motion to strike to request the Court to remove insufficient defenses as well as "redundant, immaterial, impertinent, or scandalous matter" that might otherwise prejudice a party. *E.g., Fantasy, Inc. v. Fogerty,* 984 F.2d 1524, 1527 (9th Cir.1993), *rev'd on other grounds*, 510 U.S. 517 (1994). Motions to strike are disfavored because they are "often used as delaying tactics, and because of the limited importance of pleadings in federal practice." *Colaprico v. Sun Microsystems, Inc.*, 758 F. Supp. 1335, 1339 (N.D. Ca1.1991). However, the Court may grant a motion to strike if the party can establish that the statements at issue would prejudice the moving party, or that striking the statements would streamline the case. *Fogerty*, 984 F.2d at 1528.

B. Discussion

Defendants argue the Court should strike Paragraphs, 30, 49, and 64 of the First Amended Complaint because these paragraphs contain allegations after the close of the Class Period. These paragraphs generally include allegations regarding post-Class Period Zicam user complaints of anosmia, post-Class Period studies linking Zicam use to anosmia, and post-Class Period product liability lawsuits.

Courts in this circuit have stricken as irrelevant claims in a complaint alleging fraud and insider trading outside of the class period. *See In re Clearly Canadian Sec. Litig.*, 875 F. Supp. 1410, 1420 (N.D.

Cal. 1995). Furthermore, Congress enacted the Reform Act to put an end to the practice of pleading "fraud by hindsight." *See e.g.*, *Medhekar v. United States Dist. Ct.*, 99 F.3d 325, 328 (9th Cir. 1996) (holding that Congress intended for complaints under the Reform Act to stand or fall based on the actual knowledge of the plaintiffs rather than information produced after the action has been filed).

However, "[a]lthough the class period here is short and definite, it does not determine the period of relevancy for discovery purposes. There are numerous instances in securities fraud litigation where post-offering statements, documents, or conduct have been treated as admissible evidence on the issue of scienter, intent, and knowledge." *In re Seagate Technology II Sec. Litig.*, No, C-89-2493, 1993 WL 293008, *2 (N.D. Cal. Jun 10, 1993) (unpublished opinion).

Here, the relevant inquiry is not whether, in fact, there is a statistically significant link between Zicam use and anosmia. Instead, the inquiry is whether Defendants knew that their statements were false at the time they were made. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 988 (9th Cir. 1999). Facts related to the post-Class Period research and links between Zicam and anosmia go to the former question and are irrelevant because they have no bearing on whether the Defendants knew there was a statistically significant link at the time of public disclosures. However, facts related to the numerosity of user complaints and lawsuits known to University of Colorado researchers may very well be relevant to Defendant's knowledge of user complaints.

Therefore, the Court will deny the motion to strike paragraphs 30, 49, and 64, in relation to the number of complaints and lawsuits as the Court has concluded that complaints and lawsuits may very well be relevant to Defendants' knowledge of user complaints. However the Court will grant the motion to strike portions of Paragraph 30 & 64 as they relate to Dr. Jafek's ultimate conclusions, published post-Class Period, because what Dr. Jafek's study may ultimately show is not relevant to what Defendants knew at the time statements were made and is highly prejudicial.

III. Standard of Review

Under FED. R. CIV. PRO. Rule 12(b)(6), the court will not dismiss a complaint unless it appears beyond a doubt that the plaintiff can prove no set of facts to support the claim that would entitle the plaintiff to relief. *Morley v. Walker*, 175 F.3d 756, 759 (9th Cir. 1999). In determining whether a complaint states a claim, all allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party, her Plaintiffs. *Wyler Summit P'ship v. Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). However, "the court [is not] required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). Additionally, while the Court's primary focus is on allegations contained in the pleadings, the Court may also consider documents attached to the complaint or incorporated by reference. *In re Northpoint Communications Group, Inc.*, 221 F. Supp. 2d 1090 (N.D. Cal. 2002).

Furthermore, judicial notice of documents filed with the Security Exchange Commission is proper in actions alleging securities fraud. *See e.g.*, *Allison v. Brooktree Corp.*, 999 F. Supp. 1342, 1352 n.3 (S.D. Cal. 1998).

Rule 9(b) also imposes particularized pleading requirements on a plaintiff alleging fraud or any claim premised on fraud such that all averments of fraud or mistake must be stated with particularity. Fed. R. Civ. Pro. 9(b) (2005). Additionally, an action brought under the Reform Act is subject to heightened pleading standards that are more rigorous than the Rule 9(b) standards. The Reform Act requires the plaintiff to "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 or 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 with respect to each act or omission alleged to violate securities law. 15 U.S.C. § 78u-4(b)(2). The required state of mind is deliberate recklessness. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 977 (9th Cir. 1999). However, if the alleged material false statement or omission is a "forward-looking statement," the required level of scienter is actual knowledge. 15 U.S.C. § 78u-5(c)(1)(B). A motion to dismiss the complaint must be granted if the complaint fails to satisfy these requirements. 15 U.S.C. § 78u-4(b)(3)(A).

In addition, the plaintiff has the burden of proving that the act or omission of the defendant

caused the loss for which the plaintiff seeks to recover damages. 15 U.S.C. § 78u4(b)(4). Section 10(b) makes it unlawful for any person "to use or employ, in connection with the purchase or sale of any security … any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate ...." 15 U.S.C. § 78j(b). Rule 10b-5 makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b-5(b).

IV. Discussion

To state a securities fraud claim, a plaintiff must allege that a defendant: (1) made a misrepresentation of fact or an omission (2) of a material fact; (3) with scienter; i.e., intent to deceive; (4) in connection with the purchase and sale of a security; (5) upon which the plaintiff relied; and (6) that the plaintiff's reliance was the proximate cause of the injury for which plaintiff seeks to recover damages. Securities Exchange Act of 1934, § 10b; *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002).

A. Misstatement or Omission of Material Fact

Under the Reform Act, to adequately allege securities fraud a complaint must specify each statement alleged to have been misleading, the reason or reasons why the statement was misleading and, if an allegation is made on information and

belief, all facts upon which that belief is formed. 15 U.S.C. 78u-4(b)(1). An omission is actionable under Section 10(b) if the omitted fact is material – that is, its disclosure to necessary to prevent another statement from being materially misleading. Id. Plaintiffs allege two general categories of statements and omissions prior to the end of the class period are actionable: statements regarding the safety of Zicam without disclosing a link between Zicam and anosmia and statements related to Zicam's commercial and financial potential. In essence, Plaintiffs contention is Defendants' knowledge of the University of Colorado study, user complaints, and four product-liability class actions gave rise to a duty to disclose and correct statements relating to Zicam's safety, profitability, and especially statements that there had been no clinical trial showing intranasal zinc gluconate gel causes anosmia.

In a similar context, courts have found adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe. *In re Carter-Wallace, Inc.*, 220 F.3d 36 (2d. Cir. 1998). *Carter-Wallace* involved a securities fraud claim, alleging that Carter-Wallace had run advertisements in medical journals in the first months of 1994 regarding its new epilepsy drug, Felbatol, and had made representations in these advertisements about the safety of the drug and the lack of adverse side effects. The complaint alleged that these representations were made despite the fact that Carter-Wallace was receiving medical reports that some patients using Felbatol had developed illnesses, including aplastic anemia, a fatal disease. Additional reports of aplastic anemia

were received in July 1994 resulting in a letter issued by Carter-Wallace and the Food and Drug Administration on August 1, 1994 recommending to doctors immediate withdrawal of patients from treatment with the drug. Following the letter there was a substantial drop in the price of Carter-Wallace common stock.

The plaintiffs in *Carter-Wallace* complained about the failure to disclose the adverse medical reports which were received before July 1994, and alleged that such failure indirectly inflated the market price of the Carter-Wallace stock. The Second Circuit held that there was no sufficient allegation of a knowing withholding of material information. There was no indication, said the court, that Carter-Wallace knew, or should have known, before August 1, 1994, of the connection between Felbatol and aplastic anemia. *Carter-Wallace, Inc.*, 220 F.3d at 42. The court stated: "Here, the early medical reports may have indicated a potential problem, but until a connection between Felbatol and any illness could be made, we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation." *Id.* The court took the view that Carter-Wallace was not dishonest or reckless in viewing the earlier reports as merely "random" instances of disease (i.e., not necessarily caused by Felbatol). The court noted: "Felbatol had, after all, survived the extensive testing process required by the FDA. *Id.* The court also stated that "Carter-Wallace's financial statements would not ... become materially misleading until Carter-Wallace had information that Felbatol had caused a *statistically significant* number of aplastic anemia deaths and therefore had

reason to believe that the commercial viability of Felbatol was threatened." *Id.* at 40 (emphasis added)

While, subsequent courts have noted *Carter-Wallace* does not provide a "bright-line pleading standard" for securities fraud claims where those claims are "based upon alleged failure to disclose adverse medical reports," other circuits have followed the reasoning in *Carter-Wallace*, concluding that Defendants must have statistically significant information before statements related to a products drug safety become material. *Oran v. Stafford*, 226 F.3d 275, 284 (3d. Cir. 2000) (holding "[b]ecause the link between the . . . drugs and heart-valve disorders was never definitively established during the relevant period even after the withdrawal data is taken into account [defendant's] failure to disclose this data cannot render its statements about inconclusiveness of the relationship materially misleading"); *see also In re Alliance Pharm. Sec. Litig.*, 279 F. Supp. 2d 171, 189 (finding there was a genuine issue of material fact regarding whether failure to include information in prospectus that test group would change in composition was a material omission, after noting "not every adverse effect in a clinical trial is automatically material, and that causation, as well as statistical significance, is key").

However, where a company is presented with statistically significant adverse medical reports, adverse clinical data, and a "consensus emerge[s] that the data" is "putting the brand at risk," then courts have found a material omission. I*n re Bayer AG Sec. Litig.*, No 03 C1V.1546 WHP, 2004 WL 2190357, *4 (S.D.N.Y. Sept. 20, 2004) (unpublished opinion). In *Bayer AG*, Defendants received

repeated and numerous adverse event reports indicating its drug Baycol, a cholesterol-lowering drug, caused rhabdomyolysis, an acute sometimes fatal serious muscle disease. However, Defendants repeatedly touted the efficacy, safety, and profitability of Baycol. In fact, the District Court noted by 1999 "adverse event reports were inundating Bayer" with 60 cases of rhabdomyolysis in the preceding 2 months in the United States. Id. Still, the District Court concluded Defendants only had a duty to correct previous statements as to Baycol's safety and future profitability as of August 2000, when Bayers' consultants met and "a consensus emerged that the data concerning Baycol's dangers 'was putting the brand at risk.'" The District Court reasoned it was only after the consensus emerged was the data on Baycol "sufficiently serious and frequent to affect future earnings." *Id.* at *10; *see also DeMarco v. DepoTech Corp.*, 32 Fed. Appx. 260 (9th Cir. 2002) (complaint failed to satisfy Reform Act pleading requirements where it alleged merely that drug manufacturing company's officers made positive statements about product's prospects after receiving negative clinical trial reports and failed to particularly identify which reports were contradicted by contemporaneous positive statements, nor any details as to how officers were made aware of said reports).

The above cases recognize that test results and user complaints are not always material, requiring disclosures. "Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols." *Pasnes v. Scios Nova Inc.*, No C 95-1693, 1996 WL 539711 *5 (N.D.

Cal. Sept. 18, 1996). The Food and Drug Administration ("FDA") similarly recognizes that experts can find test results difficult to interpret. In explaining to Congress why the FDA insists that applicants provide all test data to the agency instead of only summaries, that agency has stated:

> summary data has necessarily been processed, and that processing includes interpretation. When data is summarized, a decision must have already been made to look at it in some particular way. A review of the actual data provides the opportunity for that data to reveal information that would not be evidence from the single perspective.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 1997,: Hearing Before Subcomm. of the House Comm. on Appropriations, 104th Cong., 2d Sess. at 512 (1996) (written responses by FDA to questions from Congresswoman Kaptur).

Similarly, Matrixx conducted a double-blind study regarding Zicam and not a single case of anosmia was reported. The Amended Complaint provides the following allegations of links between Zicam and anosmia for which Defendants had knowledge: a phone conversation between a Matrixx vice-president and University of Colorado researcher discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University of Colorado study citing 11 cases of anosmia in Zicam users. Similar to *Carter-Wallace*, Plaintiffs present minimal evidence of Zicam complaints during the class period. Zicam is a homeopathic remedy, and therefore is not subject to the same FDA approval as

in *Carter-Wallace*. Nonetheless, the Court finds the adverse medical reports of Felbatol and user complaints here analogous. Simply, there is no data as to the reliability and accuracy of the user complaints. Even if there were data as to the reliability, the Court finds 12 user complaints is not statistically significant. While the Complaint cites to 165 other complaints, it fails to allege those user complaints were within the class period or that Defendants had any knowledge of the complaints. Moreover, Plaintiffs have failed to allege that during the class period, Defendants were presented with any evidence that the University of Colorado study was reliable, the methodology used, or that it was subject to peer review. Based on the foregoing, the Court finds that as of the close of the class period, Plaintiffs have failed to present evidence of 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.

B. Scienter

The complaint must also state 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 securities law. 15 U.S.C. § 78u-4(b)(2). The required state of mind is deliberate recklessness. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 977 (9th Cir. 1999). However, if the alleged material false statement or omission is a "forward-looking statement," the required level of scienter is actual knowledge. 15 U.S.C. § 78u-5(c)(1)(B).

Furthermore, the Reform Act modifies the

traditional standard 12(b)(6) – taking all allegations of material fact as true and in the light most favorable to the nonmoving party. *Gompper v. VISX Inc.*, 298 F.3d 893, 897 (9th Cir. 2002). Instead, the Ninth Circuit has held, "when determining whether plaintiffs have shown a strong inference of scienter, the court must consider all reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs." *Id.*

Even if the Court were to find an actionable omission or misrepresentation, the Court concludes the First Amended Complaint fails to allege the requisite scienter. Plaintiffs argue the Defendants acted with deliberate recklessness when failing to disclose a known link between Zicam and anosmia to falsely inflate the price of stock. Additionally, failure to disclose product liability lawsuits as a known contingency is a violation of GAAP and evidence of deliberate recklessness.

Here, the Complaint fails to allege any motive or state of mind with relation to the alleged omissions. 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 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."

Longo Decl. Ex. 1. There are no allegations Defendants disbelieved their statements as to the safety of Zicam, Defendants profited, or attempted to profit from public statements.

Furthermore, per se violations of GAAP and generally accepted standards for financial reporting alone are insufficient to state a claim for securities fraud, though evidence of the foregoing could support a strong inference of scienter when combined with other circumstances establishing fraudulent intent. *In re Commtouch Software Ltd. Sec. Litig.*, Fed. Sec. L. Rep. (CCH) ¶ 91985, 2002 WL 31417998 (N.D. Cal. 2002) (concluding complaint alleging corporation engaged in a pattern of recording revenue without regard to its ability to collect revenue stated fraud claim with requisite particularity; confidential witnesses described specific conduct which raised strong inference of at least actionable deliberate recklessness). Such circumstances include overstatements of earnings so vast as to be deliberately false and misleading with respect to the issuer's financial condition, or underreporting of accounts payable and other liabilities in such a magnitude that the intent to mislead the investing public about the issuer's financial condition clearly can be inferred. *Marksman Partners, L.P. v. Chantal Pharm. Corp.*, 927 F. Supp. 1297, 1313 (C.D. Cal. 1996) (holding "a violation of GAAP, in itself will generally not be sufficient to establish fraud, when combined with other circumstances suggesting fraudulent intent, however, allegations of improper accounting may support a strong inference of scienter"). Here, as noted above, other than the conclusory allegation there was a duty to disclose the one product liability

lawsuit filed at the time of the third quarter 10-Q. Plaintiffs have failed to allege a loss was reasonable foreseeable or any other overstatement giving rise to an inference of deliberate recklessness.

FED R. CIV. PRO. 15 provides that leave to amend complaints "shall be freely granted." As a general rule, it is an abuse of discretion for the district court to dismiss the plaintiff's complaint without first affording opportunity for amendment to state a claim for which relief can be granted. Absent unusual circumstances, "[d]ismissal without leave to amend is improper unless it is clear, upon de novo review, that the complaint could not be saved by any amendment." *Polich v. Burlington Northern, Inc.*, 942 F.2d 1467, 1472 (9th Cir. 1991). While some circuits have concluded the Reform Act has modified Rule 15's leave to amend with extreme liberality, the Ninth Circuit has held "[d]ismissal with prejudice and without leave to amend is not appropriate unless it is clear on de novo review that the complaint could not be saved by amendment." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

Given the fact Plaintiffs have alleged 165 user complaints in the First Amended Complaint, that the University of Colorado study was ultimately peer reviewed, and Defendants' knowledge during the Class Period is unclear, the Court will dismiss the First Amended Complaint without prejudice. However, Plaintiffs should take note that allegations of post-Class period user complaints, post-Class Period links between Zicam and anosmia, and post-Class Period publication of the University of Colorado study, lending it credibility, are wholly insufficient to cure the deficiencies in the First

Amended Complaint. Absent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was "sufficiently serious and frequent to affect future earnings," any amendment would be futile.

Accordingly

IT IS HEREBY ORDERED Defendants' Motion to Strike is **GRANTED IN PART AND DENIED IN PART**. (Dkt. #72)

IT IS FURTHER ORDERED Defendants' Motion to dismiss is **GRANTED.** The First Amended Complaint is dismissed **WITHOUT PREJUDICE.** (Dkt. #73).

DATED this 15th day of December, 2005.

Mary H. Murguia
United States District Judge

APPENDIX C

COURT OF APPEALS REHEARING DENIAL

FILED

DEC 23 2009

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

JAMES SIRACUSANO, Individually and on behalf of all others similarly situated, Plaintiff - Appellant, NECA-IBEW PENSION FUND, Claimant - Appellant, v. MATRIXX INITIATIVES, INC.; CARL J. JOHNSON; WILLIAM J. HEMELT, Defendants - Appellees.	No. 06-15677 DC Nos. CV 04-0886 MHM CV 04-1012 MHM O R D E R

Before: SCHROEDER, TASHIMA and BEA,

Circuit Judges.

The panel has voted to deny the petition for panel rehearing. Judges Schroeder and Bea vote to deny the petition for rehearing en banc and Judge Tashima so recommends. The full court has been advised of the petition for rehearing en banc and no judge of the court has requested a vote on en banc rehearing. *See* Fed. R. App. P. 35(f). The petition for panel rehearing and the petition for rehearing en banc are denied.

APPENDIX D

STATUTORY & REGULATORY PROVISIONS

15 U.S.C. § 78j(b) - Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange--

***

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78u-4(b)(2) - Private Securities Litigation

(b) Requirements for securities fraud actions

***

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to

each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

SEC Rule 10b-5 - Employment of Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.