No. 06-15677

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND, On Behalf of Themselves and All Others Similarly Situated,

Plaintiffs-Appellants,

vs.

MATRIXX INITIATIVES INC., et al.,

Defendants-Appellees.

Appeal From the United States District Court
for the District of Arizona
No. CIV-04-0886-PHX-MHM
The Honorable Mary H. Murguia

PLAINTIFFS-APPELLANTS' OPENING BRIEF

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SECONDARY AUTHORITIES

I. JURISDICTION

This case arises under Securities Exchange Act of 1934, §§10(b) and 20(a), 15 U.S.C. §§78j(b) and 78t(a). The district court had jurisdiction under 15 U.S.C. §78aa and 28 U.S.C. §1331. On December 15, 2005, the district court granted defendants' motion to dismiss without prejudice, but warned plaintiffs that unless they added certain allegations to their complaint, "any amendment would be futile." ER88:14.[1] Plaintiffs elected to stand on their allegations, and on March 8, 2006, the court entered final judgment, giving this Court jurisdiction under 28 U.S.C. §1291. ER89. Plaintiffs timely filed their notice of appeal on April 3, 2006. ER91.

II. ISSUES PRESENTED

1. Whether, under this Court's *de novo* review, the Complaint sufficiently alleges that defendants knowingly or recklessly made false or misleading statements about their core pharmaceutical product, when they repeatedly extolled the product's safety and efficacy despite knowing of the specific, adverse reaction it was causing among numerous users – loss of the sense of smell.

2. Whether the district court erred in establishing, as a matter of law, an arbitrary number of undisclosed user complaints, lawsuits, and expressions of

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[1] "ER__" refers to the Excerpts of Record, while "CD__" refers to numbered entries in the district court's docket.

scientific/medical alarm concerning Matrixx's core product as a legal standard for materiality, when that issue is ordinarily a contested issue left for trial.

III. STANDARD OF REVIEW

A complaint's dismissal is reviewed *de novo*. *Howard v. Everex Sys.*, 228 F.3d 1057, 1060 (9th Cir. 2000). On review, the Court accepts the complaint's well-pleaded allegations as true and construes them in the light most favorable to plaintiffs. *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.* ("*Am. West*"), 320 F.3d 920, 925 n.2 (9th Cir. 2003). "A complaint should not be dismissed unless it appears beyond a doubt that the plaintiff cannot prove any set of facts in support of the claim that would entitle him or her to relief." *Id*. at 931.

Although a ruling on a motion to strike ordinarily is reviewed for an abuse of discretion, if the district court's grant effectively dismissed all of plaintiff's legal claims, such a determination is reviewed *de novo*. *Yamaguchi v. United States Dep't of the Air Force*, 109 F.3d 1475, 1481-82 (9th Cir. 1997).

IV. STATEMENT OF THE CASE

A. Nature of the Case

This is a securities fraud class action brought by lead plaintiff NECA-IBEW Pension Fund on behalf of investors who purchased securities of Matrixx Initiatives Inc. ("Matrixx" or the "Company") between October 22, 2003, and February 6, 2004

(the "Class Period"). ER68:¶1.[2] The Matrixx shares plaintiffs purchased were inflated during the Class Period as a result of defendants' fraud. ER68:¶¶72-73. Defendants-appellees are Matrixx and three of its top executives: Carl Johnson (Chief Executive Officer ("CEO") and President), William Hemelt (Chief Financial Officer ("CFO")), and Timothy Clarot (Vice President and Director of Research and Development). ER68:¶¶16-20.

Plaintiffs allege that throughout the three-and-a-half-month Class Period, defendants made a series of false and misleading public statements about the safety and efficacy of Matrixx's core product, an intranasal cold remedy called "Zicam," despite knowing – via explicit warnings from several medical researchers, as well as from Zicam users themselves, and product liability lawsuits – that Zicam and its zinc-based active ingredient were being linked with the sudden onset of a terrible condition known as "anosmia" – loss of the sense of smell. *See, e.g.*, ER68:¶¶2-5, 7, 9.

Ultimately, on February 6, 2004, the national news program *Good Morning America* aired a broadcast that featured a medical researcher and Zicam research results, that reported on the adverse health risks associated with Zicam, and that noted

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[2] "ER68:¶__" refers to paragraphs in the operative Consolidated Amended Complaint for Violation of the Federal Securities Laws (hereafter "Complaint"). The Complaint, and a "Notice of Errata" to which it was attached, comprise docket number 68.

at least four lawsuits had been filed alleging Matrixx's products caused anosmia. ER68:¶8. Following the broadcast, Matrixx's common stock price plunged nearly 24% in just one day, on unusually heavy trading volume. ER68:¶8. This securities-fraud suit followed. CD1.

B. Course of Proceedings

Purchasers of inflated Matrixx securities filed suit on April 29, 2004. CD1. After briefing by various lead-plaintiff candidates, the court appointed institutional investor NECA-IBEW Pension Fund as statutory "lead plaintiff," appointed plaintiff James Siracusano as "named plaintiff," and approved the plaintiffs' choice of liaison and lead counsel. CD59.

Plaintiffs filed their consolidated complaint on March 4, 2005. CD67. Because a word-processing error had inadvertently deleted a portion of that complaint's ¶7 and all of its ¶8, plaintiffs soon filed a "Notice of Errata" attaching a corrected complaint. ER68. That attachment comprised the operative Complaint before the district court, and remains the operative Complaint here.[3]

After briefing and oral argument, the district court granted defendants' motion to dismiss without prejudice on December 15, 2005. ER88:14. It noted, however,

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[3] Because the district court clerk never separated the corrected Complaint from the Notice of Errata, the Complaint remains filed as part of ER68.

that any amendment would be futile unless plaintiffs added certain "statistical" allegations concerning Zicam. *Id*.

Plaintiffs elected to stand on their Complaint, and on March 8, 2006, the district court entered final judgment. ER89. Plaintiffs timely appealed on April 3, 2006. ER91.

C. The Disposition Below

As a threshold matter, the court granted in part and denied in part defendants' motion to strike Complaint ¶¶30, 49, and portions of ¶64 because the paragraphs contained descriptions of various post-Class Period events relating to Zicam. ER88:5. The court ruled that facts describing post-Class Period research and links between Zicam and anosmia were "irrelevant" and had "no bearing" on defendants' Class Period knowledge, *id*., and were thus properly struck. ER88:6. On the other hand, facts relating to the overall numbers to date of (a) Zicam user complaints and (b) Zicam-related lawsuits were not struck, as they "may very well be relevant to Defendants' knowledge of user complaints." *Id*.

Moving on to whether the Complaint satisfactorily alleged misstatements (or omissions) of material fact, the court decided that the adverse information about Zicam-induced anosmia that defendants received was immaterial as a matter of law. ER88:8-12. Relying upon the Second Circuit decision *In re Carter-Wallace Sec. Litig.* ("*Carter-Wallace II*"), 220 F.3d 36 (2d Cir. 2000), the court held that unless

defendants were aware of "statistically significant" information about Zicam's link to anosmia, the alleged links shown by documented test results compiled by doctors and numerous user complaints simply were immaterial – and thus did not require disclosure. ER88:8-11. The court decided that "12 user complaints" were "not statistically significant." ER88:11. The "165 [sic] other complaints" cited in the Complaint were irrelevant, for they were apparently unearthed after the Class Period. *Id.*[4] Allegations about a University of Colorado Zicam study failed to include "evidence" that the study "was reliable, the methodology used, or that it was subject to peer review" at the time. ER88:12.

The court also briefly considered defendants' scienter, and held that plaintiffs had not shown defendants' "motive" in omitting the truth about Zicam, nor presented allegations showing that defendants "disbelieved" their public statements about

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[4] The district court's recitation of just "165 other" user complaints apparently stems from the partial total recounted at ER68:¶30 ("over 100 cases" for Dr. Bruce Jafek, and "approximately 65 patients" for Dr. Miriam Linschoten). Actually, in addition to the "165 other" cases noted by these two University of Colorado researchers, the Complaint also alleges ***another 297*** user complaints – via filed lawsuits against Matrixx. *See* ER68:¶49 (setting forth in table form the Zicam-related lawsuits filed from October 2003 through February 2005). Note that although ER68:¶49 mentions in text "approximately 284 individuals" (the number is actually 285), that description is limited to the lawsuits filed "through October 2004." *Id.* The spreadsheet table at ¶49 tabulates another 12 plaintiffs in 6 more lawsuits dating from November 2004 through February 2005. *Id.* Those 12 plus 285 equals 297.

Zicam's safety – or that defendants had attempted to "profit" from them. ER88:12-13.[5]

Finally, the court addressed possible amendment. It conceded that because "165 [sic] user complaints" ***had*** eventually come to light, and that the University of Colorado study ***was*** ultimately peer-reviewed, defendants' Class Period knowledge was "unclear." ER88:14.[6] Amendment – albeit a very specific type of amendment depending upon court-delineated statistics – was therefore possible. *Id*. But plaintiffs needed to bring these allegations into the Class Period, said the court; absent allegations that defendants "***knew*** there was a definitive and statistically significant link between Zicam and anosmia" during the Class Period, the court believed any amendment would be futile. *Id*. (court's emphasis).

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[5] Narrowing their appeal, plaintiffs do not address the court's dismissal of allegations that Matrixx violated Generally Accepted Accounting Principles ("GAAP") by failing to properly reserve for potential liability stemming from Zicam-related losses. ER88:13-14.

[6] Again, the actual number of Zicam user complaints that eventually surfaced – at least by the time plaintiffs filed their Complaint – was closer to ***462***: the sum of the "165 other" the court mentioned and the 297 plaintiffs filing lawsuits, tabulated at ER68:¶49.

V. STATEMENT OF FACTS

A. Matrixx's Core Business: Zicam Cold Remedy

Matrixx develops, manufactures, and markets over-the-counter pharmaceuticals. ER68:¶2. Matrixx's core brand during the Class Period – through its wholly-owned subsidiary Zicam, LLC – was a line of common-cold products comprising 100% of Matrixx's sales, gross profits, and growth. *Id*. Within that core product line, "Zicam Cold Remedy" accounted for approximately 70% of sales overall. *Id*. The Cold Remedy could be applied in several forms, including a nasal spray and nasal gel. *Id*. Matrixx marketed it as the "only nasal product on the market that has been clinically proven to reduce the duration of the common cold." *Id*.

It is that intranasal version of Zicam Cold Remedy (hereafter "Zicam") that lies at the center of this action.

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

As described below, defendants knew both before and during the Class Period that Zicam use was being linked with loss of smell in numerous users. ER68:¶¶24-31, 49.

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

Dr. Alan Hirsch, M.D. and F.A.C.P., recognized a possible link between Zicam nasal gel and loss of smell in "a cluster" of his patients in 1999. ER68:¶25. In December 1999 – nearly four years before the Class Period began – Dr. Hirsch called Matrixx's customer service line to inquire about the amount of zinc in Zicam's nasal gel. *Id*.

Dr. Hirsch spoke with a "Mr. Laundau" at Matrixx, and told him about at least one patient who had developed anosmia after using Zicam in the absence of a cold. *Id*. He also told Laundau of previous studies demonstrating the problems associated with the intranasal application of zinc. *Id*. Dr. Hirsch volunteered to conduct a clinical study on the possible Zicam-anosmia link, but Laundau turned him down. *Id*.

2. Dr. Miriam R. Linschoten, Ph.D., of the University of Colorado's Health Sciences Center and The Rocky Mountain Taste and Smell Center ("RMTSC"), Discussed with Defendant Clarot in September 2002 the Link Between Zicam Use and Anosmia

Defendant Timothy Clarot, Matrixx's Vice President of Research and Development, actually reached out to Dr. Linschoten in September 2002 concerning Zicam's link with anosmia. ER68:¶26. Clarot had called Dr. Linschoten because one of the several patients she had been treating at the RMTSC for loss of smell following Zicam use had also complained to Matrixx. *Id*. Clarot admitted to Dr. Linschoten that

Matrixx had also received ***additional*** complaints from other consumers who experienced loss of smell following their use of Zicam nasal gel. *Id*. In fact, Matrixx had been receiving those complaints as early as 1999. *Id*.

Dr. Linschoten told Clarot of her concerns that the over-the-counter Zicam contained no warnings that it could cause users to lose their sense of smell. *Id.* She further noted previous studies that linked zinc sulfate to loss of smell. *Id*. Dr. Linschoten then offered to send information about those studies to Clarot, *id*., which she did on September 20, 2002. ER68:¶27.

Dr. Linschoten's September 20, 2002, e-mail to Vice President Clarot included abstracts on the link between zinc sulfate and loss of sense of smell – pointing out that zinc's toxicity had been confirmed by studies dating back to the 1930s, as well as from work with fish in the early 1980s. *Id*. Following his receipt of that e-mail, Clarot again telephoned Dr. Linschoten and invited her to participate in upcoming animal studies Matrixx was planning. *Id*. She declined, explaining that her focus was on human research and not animal research. *Id*.

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

As of September 2003 – one month before the Class Period – Dr. Jafek had observed ten patients suffering from anosmia following Zicam use. ER68:¶28.

Together with Dr. Linschoten and a second colleague (Bruce Murrow, also from Colorado's Department of Otolaryngology[7] (ER68:¶64)), Dr. Jafek planned to submit the trio's findings via a September 20, 2003, poster presentation to the American Rhinologic Society. ER68:¶28. Prior to the September conference, the Society posted the scheduled presentations in abstract form. *Id*. The abstract for the Jafek-Linschoten-Murrow presentation was entitled "Zicam® Induced Anosmia." *Id*.

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

Before the researchers could make their presentation to the Society, on September 12, 2003, Matrixx sent a letter to Dr. Jafek – signed by defendant Clarot – informing Dr. Jafek that he could not name either Matrixx or its products in the poster. ER68:¶29. The letter specified that "as a legal matter," Dr. Jafek did "not have their permission to use their company name or product trademarks." ER68:¶¶4, 64. After

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

consulting with the University of Colorado's attorney, Dr. Jafek sought Matrixx's permission to use the names – which Matrixx denied in a second letter. ER68:¶29. Dr. Jafek then cut out all instances of the word "Zicam" from the poster, and presented it to the American Rhinologic Society in its redacted form. *Id*.

4. Numerous Zicam Users File Personal Injury Lawsuits Against Matrixx, Complaining that the Nasal Product Caused Their Loss of Sense of Smell

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

- On October 14, 2003, two plaintiffs sued Matrixx in Michigan federal court, in *Christensen, et al. v. Matrixx Initiatives, Inc., et al.*, No. 4:03-cv-0146-HWB (W.D. Mich.). *Id*.

- On December 8, 2003, a plaintiff sued Matrixx in California state court, in *Nelson v. Matrixx Initiatives, Inc., et al.*, No. YC048136 (Cal. Super. Ct. – Los Angeles). *Id*.

- On December 18, 2003, a plaintiff sued Matrixx in Alabama state court, in *Sutherland v. Matrixx Initiatives, Inc., et al.*, No. CV2003-1635-WHR (Ala. Cir. Ct. – Etowah). *Id*. The case was later removed to Alabama federal court (No. 4:2004cv00129 (N.D. Ala.). *Id*.

- On January 23, 2004, five plaintiffs sued Matrixx in Arizona state court, in *Bentley, et al. v. Matrixx Initiatives, Inc., et al.*, No. CV2004-001338 (Ariz. Super. Ct. – Maricopa). *Id*. The number of plaintiffs in *Bentley* eventually grew to 266, through consolidation of later suits. *Id*.

The foregoing four lawsuits are just the Zicam-related personal injury actions filed ***before*** the Class Period's end on February 6, 2004, when Matrixx was still

insisting Zicam was perfectly safe. ER68:¶44. Matrixx's Securities and Exchange Commission ("SEC") filings later revealed that from late 2003 through October 2004, ***over 280 individuals*** sued Matrixx, alleging that Zicam had damaged their sense of smell. ER68:¶49. The chart in the Complaint at ¶49 compiles these lawsuits, as well as another half dozen lawsuits in late 2004/early 2005 brought by an additional 12 plaintiffs. *Id*. All told, by February 22, 2005, nearly 300 individuals who were struck with anosmia after using Zicam had sued Matrixx in 26 lawsuits. *Id*.

C. Despite Knowing that Zicam Was Blamed for Severely Damaging Some Users' Sense of Smell, During the Class Period Defendants Made a Series of False and Misleading Public Reassurances Concerning Zicam's Supposed Safety, and Falsely Denied any Link to Loss of Sense of Smell

Despite knowing of Zicam-related anosmia claims dating back to 1999 (as demonstrated in both the Dr. Hirsch telephone call and by Clarot's September 2002 admission to Dr. Linschoten), of the September 2003 Jafek-Linschoten-Murrow presentation to the American Rhinologic Society, and of the burgeoning number of Zicam-related personal injury lawsuits filed against Matrixx, throughout the Class Period defendants issued a series of false and misleading statements concerning Zicam's safety and what the Zicam product line portended for the Company's financial success. ER68:¶¶32-41.

On October 22, 2003, Matrixx issued a press release announcing third-quarter 2003 operational results. ER68:¶32. Defendant Johnson used the occasion to trumpet

the promise of the Zicam brand: It was "poised for growth" in the upcoming cough and cold season for several reasons, including what its efficacy and profitability meant to Matrixx's retail partners: "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." *Id*.

The following day on a conference call, Johnson assured analysts who followed Matrixx that the Company was "extremely encouraged at this point in time" due to the "very strong momentum" heading into the cough and cold season. ER68:¶33. The force driving that momentum was Zicam:

> [W]hat 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.

Id. Indeed, Matrixx was "extremely well positioned for a successful 2003/2004 cough/cold season" – so much so that it expected revenues for the full year to dramatically rise "up in excess of 50%." ER68:¶34.

On November 12, 2003, Matrixx formally filed its third-quarter 2003 results on Form 10-Q with the SEC. ER68:¶35. Defendants Johnson and Hemelt signed the filing. *Id*. Although the *Christensen* lawsuit complaining of Zicam-linked anosmia in

two users had already been filed the previous month (ER68:¶49), Matrixx's 10-Q omitted that fact. ER68:¶35.[8]

Instead of disclosing the anosmia reports about which it already knew, Matrixx simply warned of the possible consequences from a product-liability claim against it – even a non-meritorious one:

> 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 reducing market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

ER68:¶35. Johnson and Hemelt also signed the quarterly report's certification pursuant to §302 of the Sarbanes-Oxley Act of 2002, representing that to their

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[8] Matrixx was served with the *Christensen* lawsuit on October 23, 2003 – well before its November 12, 2003, Form 10-Q omitting any mention of the suit. *See* entry Number Three of *Christensen*'s PACER docket, case No. 4:03-cv-0146-HWB, Western District of Michigan. Although this fact is not pleaded in the Complaint, the Court may take judicial notice of the docket entry. *Duckett v. Godinez*, 67 F.3d 734, 741 (9th Cir. 1995). *See* Fed. R. Evid. 201(f) (notice "may be taken at any stage of the proceeding"); *see also* Advisory Committee's note to Fed. R. Evid. 201(f) ("In accord with the usual view, judicial notice may be taken at any stage of the proceedings, whether in the trial court or on appeal.").

Moreover, the record shows that during the Class Period, Matrixx ***answered*** at least two of the Zicam-related anosmia lawsuits. The January 30, 2004, *Dow Jones Newswire* (which defendants placed before the district court at Exhibit 7 to CD74) reported that Matrixx answered the *Christensen* complaint on January 9, 2004, and answered the *Sutherland* complaint on January 22, 2004. *See* CD74/Ex. 7:2.

knowledge, the report did not contain any untrue statements of material fact "or ***omit*** to state a material fact necessary to make the statements made" not misleading. ER68:¶36 (emphasis added).

The misleading good news continued. On January 7, 2004, Matrixx issued a press release that noted its "expanded line of Zicam® Cold Remedy Products" and revised its financial guidance for 2003 results even higher. ER68:¶37. Instead of the 50%-plus growth Matrixx had told analysts about back on October 23, 2003, total 2003 revenues were now expected to have grown "by greater than 80 percent." *Id*. The chief reason? People were catching more colds than previously anticipated. *Id*.

A major financial news service put a temporary damper on Matrixx's rosy pronouncements. On January 30, 2004, after the close of ordinary trading, the *Dow Jones Newswires* reported that the Food and Drug Administration ("FDA") was looking into complaints that "an over-the-counter common-cold medicine manufactured" by a Matrixx unit "may be causing some users to lose their sense of smell." ER68:¶40. *Dow Jones* revealed that the allegations had been made in "at least three lawsuits." *Id*. In fact, by the time of the January 30 *Dow Jones* piece, four Zicam-related lawsuits had been filed against Matrixx by nine plaintiffs. ER68:¶49. Following the *Dow Jones* revelation, Matrixx's stock price dropped from $13.55 per share on January 30 to $11.97 per share on February 2, 2004. ER68:¶41.

Matrixx responded to the *Dow Jones* piece with a February 2, 2004, press release vehemently denying any Zicam-anosmia connection. ER68:¶38. Any statements "alleging that intranasal Zicam products cause anosmia (loss of smell)," blasted Matrixx, "***are completely unfounded and misleading***." *Id*. (emphasis added). Indeed, "***[i]n no clinical trial*** of intranasal zinc gluconate gel products ***has there been a single report*** of lost or diminished olfactory function (sense of smell). Rather, the ***safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established*** in two double-blind, placebo-controlled, randomized clinical trials." *Id*. (emphasis added). Matrixx suggested the blame might lie elsewhere, as a "multitude of environmental and biologic influences are known to affect the sense of smell." *Id*. The chief suspect, Matrixx suggested, was the common cold itself: "As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia." *Id*.

Following Matrixx's denials, its stock price rose back to $13.40 on February 3, 2004. ER68:¶41.

D. The Dramatic Truth About Zicam's Link to Loss of Sense of Smell Is Revealed to a Nationwide Audience, and Matrixx's Stock Plummets

On February 6, 2004, the link between Zicam and anosmia was revealed to a nationwide television audience. ER68:¶42. On the nationally broadcast news program *Good Morning America* that day, reporter John Ferrugia told viewers about a

woman named "Linda" who claimed that Zicam gel had caused her anosmia. *Id*. Ferrugia noted that Linda's claim was not an isolated one: "Dr. Bruce Jafek has discovered more than a dozen patients with the same troubles as Linda . . . after using the Zicam product." *Id*. The reporter tallied the burgeoning number of lawsuits against Matrixx alleging Zicam-caused anosmia: "Well, in fact, there have been, so far, four lawsuits." *Id*. But those four were not the only ones on the horizon, as "[o]thers are being prepared, anywhere from California to Michigan." *Id*.

Following the *Good Morning America* piece, Matrixx's common stock plummeted from the previous day's $13.05 per share to close at $9.94 on February 6, on unusually heavy trading volume. ER68:¶43. Investors saw nearly one-quarter of Matrixx stock's value erased, for the plunge represented a one-day drop of 23.8%. *Id*.

E. Epilogue: Defendants' Post-Class Period Admissions Contradicted Their Earlier Representations, While the Numbers of Zicam-Related Anosmia Sufferers Climbed Higher and the *American Journal of Rhinology* Published the University of Colorado Researchers' Findings

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

The admission came in a Form "8-K" filed with the SEC, in which Matrixx explained that it had convened a two-day meeting of "physicians and scientists to

review current information on smell disorders" as a direct response to "a poster presentation at the American Rhinological Society in September 2003." ER68:¶45. The Matrixx-convened panel concluded that there was "***insufficient evidence at this time to determine if zinc gluconate***, when used as recommended, ***affects a person's ability to smell***." ER68:¶46 (emphasis added).

Reporter John Ferrugia, who had earlier reported on the Zicam-anosmia link for *Good Morning America*, filed a piece on Web site *TheDenverChannel.com* (an ABC News affiliate) pointing out the contradiction. ER68:¶47. His article, entitled "Zicam Admits No Studies Done on Loss of Smell," reported that Matrixx had recently formed a medical advisory panel, and that "[t]he makers of the nationally advertised cold remedy Zicam ***now admit that they don't know*** if their nasal gel could cause loss of smell." *Id.* (emphasis added). "Matrixx Initiatives[] first told us its studies showed the product [was] safe, but it will now begin animal and human testing to determine whether its zinc compound could be harmful when sprayed in the nose, causing some to lose their sense of smell." *Id*. "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." *Id*. Matrixx expected that the results of the planned "'animal and human studies'" on Zicam and anosmia would not be available for another 12 months, reported Ferrugia. *Id*.

"'It seems to me that those studies should have been done before they put the product on the market,'" Dr. Jafek told Ferrugia. ER68:¶47. He was also concerned about consumers who may be still at risk, Dr. Jafek said, because Matrixx was insisting on leaving Zicam nasal gel on store shelves until the studies' completion. *Id*. "'It would seem that it would either be reasonable to remove the product from the market pending the additional study recommended by the scientific panel or at least put a warning label so people can be aware of this problem,'" said Dr. Jafek. *Id*. He provided his own warning to consumers: "'If you want to use this product to possibly shorten duration or severity of your cold, do so but be aware that it may cause a loss of smell.'" *Id*.

By April 2004, Dr. Jafek had evaluated ***over 100 cases*** of anosmia following Zicam use. ER68:¶30. Dr. Linschoten estimates she has been in contact with approximately ***65 patients*** who lost their sense of smell following application of Zicam nasal gel. *Id*. She has "no doubt" that the Zicam had an "immediate effect" upon the patients, for they complained of an "immediate, severe burning" following their Zicam application, followed by a loss of sense of smell. *Id*. While some patients partially regained their sense of smell after several months, none has completely recovered. *Id*. And, adding to the 9 plaintiffs who had sued Matrixx during the Class Period, another 288 plaintiffs filed Zicam-related lawsuits against Matrixx throughout 2004 and early 2005. ER68:¶49.

In its May/June 2004 issue, the *American Journal of Rhinology* published the University of Colorado researchers' findings that "[z]inc ions are toxic to olfactory epithelium," and that "[r]eports of severe hyposmia with parosmia or anosmia appear to be related to the intranasal use of zinc gluconate [Zicam Cold Remedy]." ER68:¶30.[9]

VI. SUMMARY OF ARGUMENT

Under this Court's *de novo* review, the Complaint alleges with sufficient particularity defendants' false and misleading statements and omissions, as well as the myriad facts bolstering a strong inference of defendants' actual knowledge and deliberate recklessness. The Complaint alleges a paradigmatic case of securities fraud, for defendants deliberately misled investors about the strong (but undisclosed) link between Matrixx's core Zicam product and a terrible side effect being reported to defendants via myriad channels.

The district court dismissed this case on the ground that the numerous adverse reports defendants had received were immaterial as a matter of law, because they did not rise to the level of "statistical significance." Just what number of lost-sense-of-smell complaints ***would*** be statistically significant, the district court never said. It said

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[9] The *American Journal of Rhinology* "publishes peer reviewed original articles, review manuscripts and abstracts of important world-wide research publications on the nose." *See* http://www.oceansidepubl.com/rhinology.html.

there were simply not enough, relying upon the Second Circuit's holding in *Carter-Wallace II*, 220 F.3d 36, that the number of reports linking a specific adverse reaction to the drug Felbatol did not rise to a statistically significant level until the reports reached a certain number; *see also In re Carter-Wallace, Inc.* ("*Carter-Wallace I*"), 150 F.3d 153, 157 (2d Cir. 1998) (company's statements did not become materially misleading until it knew of statistically significant number of drug-reaction reports).

The district court erred, for it erected the sort of artificial, bright-line materiality test forbidden both by Supreme Court authority as well as Circuit precedent. *See Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988); *see also Am. West*, 320 F.3d at 934 ("we decline to adopt a bright-line rule" for materiality). Whether the numerous reports to defendants of lost sense of smell following Zicam use rose to a material level should not have been decided by the court on a Rule 12(b)(6) motion. Rather, the inquiry required a delicate assessment of the inferences reasonable shareholders would draw from the facts – which assessment is peculiarly suited for a trier of fact. *Am. West*, 320 F.3d at 934.

In addition to its bright-line materiality error, the court further erred because it misunderstood – and thus misapplied – the concept of "statistical significance." "Statistical significance" is a technical term that concerns only whether an observed relationship is real, or is the product of random error. It requires a formal study, and calculations utilizing test populations, hypotheses, and levels of significance. But the

district court did not even purport to conduct a proper test. Instead, it used the term "statistical significance" to denote what it believed would be a sufficiently high number of anosmia complaints. Ironically, the *Carter-Wallace II* panel made the same mistake – picking out of thin air the number of adverse reports that needed to be communicated to defendants before they were obligated to disclose the damaging truth.

Finally, even if the *Carter-Wallace II* panel's (purported) employment of statistical significance was proper at the pleading stage of a securities-fraud action, the panel's ultimate conclusion actually supports plaintiffs here. The *Carter-Wallace II* defendants had initially received just four adverse reports linked to Felbatol, among a much larger number of unrelated reports. Later, when another six adverse reports linked to Felbatol appeared, the number of adverse events ***had*** become statistically significant. *Carter-Wallace II*, 220 F.3d at 40-41. In contrast, the ***over 20*** adverse reports defendants received here each concerned the same, unique reaction – loss of sense of smell – and each was allegedly caused by Zicam.

VII. ARGUMENT

A. Given the Sheer Amount of Adverse Information Communicated to Defendants Concerning the Link Between Zicam and Anosmia, Their Class Period Statements and Omissions Were Knowingly or Recklessly False and Misleading

Exchange Act §21D(b)(1) says that whenever plaintiffs allege defendants made false or misleading statements, or omitted information necessary to make their statements not misleading, the complaint shall "specify each statement alleged to have been misleading" and the "reasons why the statement is misleading." 15 U.S.C. §78u-4(b)(1).

Moreover, plaintiffs must plead with particularity facts raising a strong inference of the defendants' state of mind, or scienter. 15 U.S.C. §78u-4(b)(2). "In this Circuit, the required scienter is 'deliberate or conscious recklessness."' *Am. West*, 320 F.3d at 937 (quoting *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 979 (9th Cir. 1999)). This Court holds that scienter allegations must be collectively considered. *Id*. at 938; *see also Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1234 (9th Cir. 2004).

As described in the Statement of Facts *supra* and argued below, the Complaint easily met these requirements, and the district court committed reversible error in holding otherwise.

1. The Complaint Alleges with Particularity Defendants' False and Misleading Statements and Omissions

Defendants' false statements relating to Zicam concerned three areas: (i) that Zicam was an efficacious product that would drive the momentum of Matrixx's rising revenues (ER68:¶¶32-34, 37); (ii) that ***if*** product-liability claims – even non-meritorious ones – ***were*** to arise from use of a Matrixx product, serious financial consequences could follow (ER68:¶35); and (iii) that any statements alleging that intranasal Zicam products caused anosmia were "completely unfounded and misleading," as no clinical trial of Zicam had resulted in a single report of lost or even diminished sense of smell. ER68:¶38.

Given the right set of facts, falsity is not difficult to plead. Allegations of "'specific problems undermining a defendant's optimistic claims suffice to explain how the claims are false.'" *Cooper v. Pickett*, 137 F.3d 616, 626 (9th Cir. 1998) (quoting *Fecht v. Price Co.*, 70 F.3d 1078, 1083 (9th Cir. 1995)). The "specific problem" undermining defendants' statements here could not have been more stark: at the time they spoke, ***Zicam was causing an alarming number of its users to lose their sense of smell***. ER68:¶¶24-31, 49.

The allegation of that specific, undisclosed problem must be accepted as true at this stage. *Am. West*, 320 F.3d at 935 ("the District Court failed to accept Plaintiffs' allegations as true"). That allegation suffices on its own to explain how defendants' Class Period Zicam-related statements were false and misleading. *Cooper*, 137 F.3d

at 626; *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 502 (9th Cir. 1992) (product's undisclosed technical problems undermined defendants' claims of "strong interest" and "high acclaim"). Plaintiffs pleaded with particularity that, because Zicam was actually harming consumers who were squirting it into their nasal passages, the product was ***not*** efficacious, and could ***not*** be relied upon to continue driving Matrixx's revenues to dizzying increases. ER68:¶¶32-34, 37. Similarly, because Zicam was causing some users to lose their sense of smell, Matrixx's top executives could ***not*** have been "extremely encouraged" or realistically claiming "very strong momentum" heading into a cold and cough season (ER68:¶33) – when, ironically, increasing numbers of Zicam users meant that even more people would be exposed to the risk of anosmia.

But plaintiffs were able to plead much more than the plain fact that Zicam could cause anosmia. They also alleged a barrage of complaints coming into Matrixx before and during the Class Period, both from numerous Zicam users who allegedly experienced the horrors of anosmia as a result of the zinc-based product, as well as from those users' doctors who were researchers in the field.

For example, there was the initial "cluster" of patients observed by Dr. Alan Hirsch in 1999, prompting his telephone call to Matrixx in December of that year. ER68:¶25. Dr. Hirsch told Matrixx about at least one of those injured patients. *Id.*

Dr. Hirsch even volunteered to conduct a clinical study on the issue, but was turned down. *Id*.

There were also the "several" patients of Dr. Linschoten who suffered Zicam-induced anosmia prior to September 2002, and her conversation that month with defendant Clarot on the issue. ER68:¶26. Importantly, it was Clarot who had first reached out to Dr. Linschoten, not the other way around – for one of Dr. Linschoten's patients at the RMTSC ***had also complained to Matrixx***. *Id*. In his conversation with Dr. Linschoten, Clarot made the startling admission that Matrixx had already been receiving lost-sense-of-smell complaints from other Zicam users dating back to 1999. *Id*. Dr. Linschoten later e-mailed Clarot several abstracts on the link between zinc sulfate and anosmia – and pointed out that zinc's toxicity had been confirmed in studies dating back to the 1930s. ER68:¶27. Clarot responded by inviting Dr. Linschoten to participate in upcoming animal studies. *Id*. In short, Matrixx's Director of Research and Development was undeniably aware of Zicam's alleged link to anosmia.

But there were even more injured Zicam users who came to Matrixx's attention during the Class Period. There was the group of patients that Dr. Jafek observed at the University of Colorado – the same group featured in the research contained in the September 2003 poster presentation submitted to the American Rhinologic Society, that was later published in the *American Journal of Rhinology*. ER68:¶¶28, 30. And

even those patients were not the end of the procession of Zicam-injured users – there were also the nine plaintiffs who filed four lawsuits against Matrixx during the Class Period. ER68:¶49. Given the quantifiable numbers of complaints by Zicam users and several medical professionals dating back to 1999 and continuing up through the Class Period, Matrixx's dogged insistence in its January 2, 2004, press release that any allegations of Zicam-induced anosmia were "completely unfounded" (ER68:¶38) was patently misleading.[10]

Misleading, as well, was Matrixx's feeble warning in its November 2003 SEC filing that a product-liability claim – even a non-meritorious one – ***could*** have a "material adverse effect" on its brands and goodwill. ER68:¶35. The statement was doubly false: Not only did Matrixx fail to acknowledge that it had already been sued by two plaintiffs in the *Christensen* lawsuit, but its warning omitted the fact that the University of Colorado study of numerous Zicam-anosmia complaints meant that it was highly likely more lawsuits were coming. *Id*. In other words, Matrixx told investors that future product liability suits – even those without merit – could be a big

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[10] In addition to Matrixx itself, each of the three individual officer defendants are responsible for the press release's contents under this Circuit's "group publication" rule. It is reasonable to infer that a corporation's annual reports, press releases, or other forms of "group published" information are the collective actions of its officers and directors. *Blake v. Dierdorff*, 856 F.2d 1365, 1369 (9th Cir. 1988); *Wool v. Tandem Computers, Inc.*, 818 F.2d 1433, 1440 (9th Cir. 1987).

problem, ***at a time when the problem already existed***. "'To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit.'" *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 515 (9th Cir. 1991) (quoting *Huddleston v. Herman & MacLean*, 640 F.2d 534, 544 (5th Cir. 1981), *aff'd in part and rev'd in part on other grounds*, 459 U.S. 375 (1983)); *accord In re Westinghouse Sec. Litig.*, 90 F.3d 696, 709-10 (3d Cir. 1996). Defendants knew that Zicam was already in trouble when they all spoke in that filing. *Wool*, 818 F.2d at 1440.[11]

Finally, Matrixx's attempt at damage control following the January 30, 2004, *Dow Jones Newswire* piece was particularly misleading due to the Company's strong implication that day that it had conducted clinical tests for anosmia, and come up empty-handed. ER68:¶38. Matrixx asserted that "***[i]n no clinical trial*** of intranasal zinc gluconate gel products ***has there been a single report*** of lost or diminished olfactory function (sense of smell)." *Id*. (emphasis added). "Rather, ***the safety and efficacy of zinc gluconate*** for the treatment of symptoms related to the common cold

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[11] Even if this Court does not credit the "group-publication" inference, defendants Johnson and Hemelt (in addition to Matrixx itself) are responsible for the misstatements and omissions, for they signed the document. ER68:¶35. *See Howard*, 228 F.3d at 1061.

have been well established in two double-blind, placebo-controlled, randomized ***clinical trials***." *Id*. (emphasis added).

Clearly, the carefully worded statements implied that Matrixx had ***specifically*** tested for a Zicam-anosmia connection at least twice. The investing public certainly thought so: After Matrixx made the disavowals, its stock price rose from $11.97 per share on February 2 back to $13.40 on February 3. ER68:¶41. And a national news outlet two weeks later expressed outrage at the misdirection. ER68:¶47 ("Zicam Admits No Studies Done on Loss of Smell").

But, while it may have been true that neither clinical trial had yielded an anosmia reaction, even literally "true" statements can mislead, and thus be actionable, under the securities laws. *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1551 (9th Cir. 1994) (en banc); *accord Kaplan v. Rose*, 49 F.3d 1363, 1372 (9th Cir. 1994). As this Court has long recognized, "'Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors.'" *Convergent*, 948 F.2d at 512 (citation omitted). "'For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers.'" *Id*. (citation omitted). Given Matrixx's absolute knowledge of the numerous alleged Zicam-anosmia reports ***outside*** of the context of clinical trials, it was false and misleading to split hairs and focus investors' attention on "clinical trial" results.

2. The Complaint's Allegations, Viewed Both in Combination and in Plaintiffs' Favor, Support a Strong Inference that Defendants Knew Their Zicam-Related Statements (and Omissions) Were False and Misleading

Whether falsity and scienter have been adequately pleaded can be collapsed into a single inquiry, because their analyses frequently involve the same set of facts. *Am. West*, 320 F.3d at 932. Under this analysis, the same particularized facts in §VII.A.1., *supra*, that illustrate the falsity of defendants' Class Period statements discussing Zicam also establish defendants' knowledge that those statements were false or misleading.

To briefly recap: When defendants spoke to the market about Zicam in late 2003-early 2004, they already ***knew*** (but deliberately concealed) the following:

- Matrixx had been receiving complaints of Zicam-caused anosmia from consumers dating back to 1999. ER68:¶26.

- Dr. Alan Hirsch had contacted Matrixx in December 1999 to inquire about the amount of zinc in Zicam's nasal gel, after seeing a potential link between Zicam and anosmia in a "cluster" of his patients. ER68:¶25. He specifically told Matrixx about at least one patient who developed anosmia after using Zicam. *Id*. Dr. Hirsch also told Matrixx about previous studies demonstrating the problems associated with the intranasal applications of zinc. *Id*.

- Matrixx's own Vice President of Research and Development, defendant Timothy Clarot, contacted an outside researcher in the taste-and-smell field (Dr. Miriam Linschoten) in September 2002 concerning Zicam's possible link with anosmia, because one of the several patients Dr. Linschoten was treating for Zicam-induced anosmia had also complained directly to Matrixx. ER68:¶26. Dr. Linschoten relayed to Clarot her concerns that Zicam – as an over-the-counter (*i.e.*, non-prescription)

medicine – contained no warnings about possible anosmia from its use. *Id*. She then e-mailed to Clarot on September 20, 2002, more information on zinc studies dating back to the 1930s. ER68:¶27. Clearly, Matrixx took Dr. Linschoten seriously – for Clarot telephoned her again and invited her to participate in upcoming animal studies. *Id*.

- Dr. Bruce Jafek, a researcher in the University of Colorado's Department of Otolaryngology – along with Dr. Linschoten and Bruce Murrow – had prepared a poster presentation for a September 2003 conference of the American Rhinologic Society discussing ***ten patients*** who suffered anosmia following Zicam use. ER68:¶28. Matrixx responded by sending a letter to Dr. Jafek warning him not to include the name of either Matrixx or its products in the actual poster – and followed that letter up with a second one. ER68:¶29.

- Before and during the Class Period, nine Zicam users sued Matrixx for personal injuries in four separate lawsuits, alleging Zicam had damaged their sense of smell. ER68:¶49. Matrixx even answered at least two of the lawsuits during the Class Period. *See supra* n.8.

- By late January 2004, the FDA was looking into complaints that Zicam caused anosmia among some users. ER68:¶40.

The fact that defendants made statements about Zicam "when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is ***classic evidence*** of scienter." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (emphasis added); *see also Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) (collecting cases).

In addition to the foregoing allegations, the inference of defendants' knowledge is further strengthened by other facts in the Complaint. These facts, too, need to be considered in the aggregate, under a totality-of-the-circumstances analysis. *Am. West*, 320 F.3d at 938.

For instance, Zicam's importance to Matrixx as the predominant seller in the Company's ***core*** product line adds to the circumstantial evidence of defendants' scienter. *See id*. at 943-44; *Aldridge*, 284 F.3d at 84; *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). Matrixx's common-cold products comprised 100% of the Company's sales, gross profits, and growth – and within that core product line, "Zicam Cold Remedy" accounted for approximately 70% of sales overall. ER68:¶2. Defendants themselves portrayed Zicam as the product line powering Matrixx's financial engine. ER68:¶¶32-34, 37. They also warned investors that just one lawsuit – even a non-meritorious one – could have crippling effects upon the Company. ER68:¶35.

Plainly, then, Zicam's success – or lack thereof – was prominent in Matrixx's executive suites. That prominence bolsters the strong inference that defendants knew of the Zicam-anosmia link. *Am. West*, 320 F.3d at 943-44 & n.21; *In re Northpoint Commc'ns Group, Inc., Sec. Litig. & Consol. Cases*, 221 F. Supp. 2d 1090, 1104 (N.D. Cal. 2002) ("upon the laying of a proper factual foundation . . . it may be inferred that facts critical to a business's core operations or an important transaction are known to a company's responsible officers"). As this Court noted in an analogous

context, it would be "absurd to suggest" that defendants did not discuss the alarming reports coming into Matrixx. *Am. West*, 320 F.3d at 943 n.21.[12]

Further bolstering the inference of scienter is defendants' post-Class Period revelation of a damning truth, so close on the heels of contrary misstatements. *Fecht*, 70 F.3d at 1083; *see also Yourish v. Cal. Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999) (temporal proximity between misstatements/omissions and a later disclosure may "***bolster*** a complaint," even if not sufficient alone) (Court's emphasis). Recall, as late as February 2, 2004, Matrixx was reassuring the market that "[i]n ***no clinical trial***" of their Zicam intranasal zinc gluconate gel products "***has there been a single report*** of lost or diminished olfactory function (sense of smell)." ER68:¶38 (emphasis added). Rather, the product's "***safety and efficacy*** . . . have been well established in two double-blind, placebo-controlled, randomized clinical trials." *Id*. (emphasis added).

Yet within two weeks of those statements implying there had been clinical trials expressly testing for anosmia, Matrixx admitted in an SEC filing that it simply ***did not know*** whether or not Zicam ***could*** cause loss of a sense of smell. ER68:¶¶45-46.

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[12] *See also Nathenson v. Zonagen Inc.*, 267 F.3d 400, 425 (5th Cir. 2001) (product's importance to the defendant among the "special circumstances" showing scienter); *In re PeopleSoft, Inc., Sec. Litig.*, No. C 99-00472 WHA, 2000 U.S. Dist. LEXIS 10953, at *10 (N.D. Cal. May 26, 2000) ("'facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its key officers'") (citation omitted).

Indeed, it was only in response to the September 2003 Jafek-Linschoten-Murrow poster presentation that Matrixx finally convened a panel to investigate the Zicam-anosmia link – and that panel admitted that there was "***insufficient evidence at this time to determine if*** zinc gluconate, when used as recommended, affects a person's ability to smell." ER68:¶46 (emphasis added). Given that lack of certainty, Matrixx now had to conduct even further studies – both "animal and human" – on the issue. ER68:¶47.

Finally, the inferences arising from the post-Class Period (a) research article in the peer-reviewed *American Journal of Rhinology*, and (b) onslaught of Zicam-anosmia product-liability lawsuits against Matrixx are at least relevant to what defendants knew during the Class Period. *E.g.*, *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000) (evidence from 13 months past the class period, taken with other allegations, bolsters strong inference of defendants' knowledge); *Novak*, 216 F.3d at 312-13 (actions directly following class period "tend[] to support the plaintiffs' contention" of class period incidents). As plaintiffs' counsel explained at the district court hearing, the article that ultimately appeared in the peer-reviewed journal contained the same research that appeared in the earlier poster presentation. Transcript at 35:18-36:12. The Complaint's allegations are consistent with that

explanation. ER68:¶¶30, 64 (Colorado researchers' findings "were later published" in the *American Journal of Rhinology*).[13]

And although 22 of the Zicam lawsuits alleged in the Complaint were not filed until after the Class Period, surely their sheer number raises ***some*** inference that the injured consumers were complaining to Matrixx well before then. *See, e.g.*, *Plotkin v. IP Axess Inc., Etc.*, 407 F.3d 690, 698 (5th Cir. 2005) ("later-emerging facts can, in some circumstances, provide warrant for inferences about an earlier situation"). The district court conceded as much. *See* ER88:6 (partly denying motion to strike allegations of post-Class Period lawsuits as the later "lawsuits may very well be relevant to Defendants' knowledge of user complaints"). Indeed, the inference becomes much stronger in light of Dr. Linschoten's recollection that defendant Clarot

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[13] The district court abused its discretion, then, by striking the Complaint's allegations describing the Colorado researchers' post-Class Period publication of the same research that Matrixx responded to during the Class Period. The court thought that the researchers' "ultimate conclusions, published post-Class Period" were not relevant to what defendants knew ***during*** the Class Period (ER88:6), but in light of the allegation that the research was the ***same***, that conclusion is insupportable. *E.g.*, *Delno v. Mkt. St. Ry. Co.*, 124 F.2d 965, 967 (9th Cir. 1942) ("Discretion . . . is abused when the judicial action is arbitrary, fanciful or unreasonable . . . [or] where no reasonable man [or woman] would take the view adopted by the trial court."). Surely no reasonable observer would think that a longer article, published in a peer-reviewed medical journal, on the identical subject of a medical poster presentation some months earlier, was totally irrelevant.

admitted to her in September 2003 that Matrixx had received Zicam-anosmia complaints dating ***back to 1999***. ER68:¶26.

Despite all of the foregoing allegations strongly supporting scienter, the district court ruled that defendants could not have known that their Class Period statements were false. ER88:12-13. Focusing mainly on Matrixx's September 12, 2003, warning letter to Dr. Jafek, the district court said plaintiffs' argument that the letter showed defendants' knowledge "is not well taken." ER88:13. Nor could the court see any scienter on defendants' part because they had not "profited" from their misstatements (*id*.) – presumably by selling inflated stock.

The court's scienter analysis is seriously flawed in several respects.

First, by focusing on (1) the Jafek letter and (2) defendants' ostensible lack of motivation, the court discounted the numerous other pieces of scienter evidence discussed *supra* – and which, considered in their totality, form a mosaic of scienter – if not scienter compromising actual knowledge, at the very least deliberate recklessness, in continuing to tout the efficacy of Zicam in the face of contrary facts.

Second, the court erred by completely discounting ***any*** inference in plaintiffs' favor concerning defendants' knowledge arising out of Matrixx's September 12, 2003, letter to Dr. Jafek that warned against using the Matrixx or Zicam names in the American Rhinologic Society presentation later that month. The court thought an equally reasonably inference was that defendants were "appropriately protecting

Zicam's good name and marketability." ER88:13. But that analysis is incomplete, for it acknowledges only that Matrixx was trying to protect its Zicam brand – and itself – by shooting a warning shot over the Colorado researchers' bow.

But the court's reasoning erroneously assumes that Matrixx was ***justified*** in seeking to squelch truthful information about Zicam – ignoring the Complaint's allegations showing that Matrixx knew by then that Zicam's "good name" was fast becoming tarnished. It is important to remember that Matrixx already knew that several researchers in the field had linked its core product with anosmia in at least ten patients. *See* CD74/Ex.1 at 1 ("We recently learned that you and your colleagues may be planning to make" the September poster presentation to the American Rhinologic Society.). Moreover, even prior to Matrixx's learning of the upcoming Jafek-Linschoten-Murrow poster presentation, the Company ***already knew*** that Zicam users had been complaining since 1999 about the same thing. ER68:¶26. Considered in plaintiffs' favor, the letter strongly supports an inference of an attempt at a Matrixx ***coverup*** – not a legitimate attempt at correcting misinformation.

Finally, the district court's single-minded focus on just what motivated defendants in the absence of profit-taking is simply wrong. While a defendant's "motive" to commit fraud may help bolster the scienter allegations against it, it is not required. This Court has rejected the district court's reasoning in at least two cases.

In *Hanon*, among defendants' evidence (proffered on summary judgment) of their "good faith belief" in the "accuracy" of allegedly misleading statements was the fact that the corporation's "officers did not sell their stock during the class period." 976 F.2d at 507. "This may all be true," noted this Court, but plaintiffs' countervailing evidence that the defendants were aware of undisclosed problems with the product sufficed to raise a genuine issue of material fact on the issue of defendants' scienter. *Id*.

More recently, in the *Am. West* decision, this Court rejected the idea that the scienter element of a securities-fraud claim requires that a defendant profit from the fraud: "Scienter can be established even if the officers who made the misleading statements did not sell stock during the class period." 320 F.3d at 944 (citing *Hanon*, 976 F.2d at 507). Thus, while the district court here thought it dispositive that none of the defendants attempted to profit from their public statements, "the lack of stock sales by a defendant is not dispositive as to scienter." *Id*.; *see also Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 170 (2d Cir. 2000) ("Of course, if the court decides on remand that the Complaint successfully pleaded the defendants engaged in conscious or reckless misbehavior, it need not also consider the motive and opportunity prong of scienter.").

At bottom, while no single allegation ***proves*** that during the Class Period defendants knew that Zicam caused anosmia, in combination the numerous allegations certainly raise a strong ***inference*** of defendants' deliberate recklessness or actual

knowledge. That strong inference is all that is required at this stage of the proceedings. *Am. West*, 320 F.3d at 945-46.

B. The District Court Erred in Erecting a Bright-Line Rule of Materiality Built upon the Unsupportable Conclusion that the Numerous Complaints Known to Defendants Were Not "Statistically Significant"

The district court's dismissal revolved around a central theme: Defendants had no duty to speak truthfully about the numerous cases of Zicam-related anosmia that had been reported to them until the number of injury reports reached some material, "statistically significant" level. ER88:8-12. Looking to the "similar context" of the drug-safety allegations in *Carter-Wallace II*, 220 F.3d 36, the district court explained that adverse information relating to a product's safety "is not material unless such reports provide reliable statistically significant information that a drug is unsafe." ER88:8.

As explained *infra*, the district court was wrong on several levels. First, in a securities-fraud case, especially at the motion-to-dismiss stage, the materiality of omitted information is a fact-intensive inquiry for trial considered from the viewpoint of a reasonable investor – not by importing some arbitrary measure of "statistical significance" from the field of statistics. *E.g.*, *Basic*, 485 U.S. at 231-32. Second, the district court was confused – as was the *Carter-Wallace* panel – about the entire notion of "statistical significance," and its conclusion was unsupportable under any reasonable understanding of that calculation. Finally, even if *Carter-Wallace II* did

set forth a relevant yardstick of "statistical significance" in the context of drug-product complaints, the numbers of documented complaints in this case vastly exceeded the level held to be statistically significant there.

1. The District Court Erred by Holding that the "Materiality" of the Undisclosed Zicam-Anosmia Information Could Be Resolved Under a Bright-Line Legal Test, Rather than as a Disputed Fact for Trial

The district court erred in imposing a bright-line criterion on the omitted Zicam-anosmia link known to defendants before that information could be considered "material" under the federal securities laws.

As a threshold matter, the district court did not cite – nor are plaintiffs aware of – ***any*** decisions from this Court requiring that the negative, undisclosed facts known to defendants in a securities-fraud suit be "statistically significant" before becoming "material."[14] Nor are plaintiffs aware of any decisions looking at materiality from the ***defendants'*** subjective viewpoint.

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[14] At ER88:10, the court lumped in with its "statistically significant" cases a citation to the unpublished decision of *DeMarco v. DepoTech Corp.*, 32 Fed. App'x 260 (9th Cir. 2002), but under this Court's rules, the memorandum disposition is not binding precedent. *See* Circuit Rule 36-3. Moreover, *DeMarco* does not even mention statistical significance; it simply holds that defendants' knowledge of certain adverse reports could not be ascertained due to plaintiffs' failure to allege that knowledge with particularity. 32 Fed. App'x at 262. Here, given the September 2003 warning letter to Dr. Jafek, the product liability lawsuits filed against Matrixx, and the September 2002 Clarot conversations with Dr. Linschoten, there is no doubt that defendants were aware of the adverse Zicam reports.

That absence of authority is unsurprising, for it has been long-settled that materiality is looked at objectively, from the perspective of the injured ***investors***: A fact is "material" whenever there is any substantial likelihood "'that a reasonable shareholder would consider it important,'" or that it "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)); *Am. West*, 320 F.3d at 934. Moreover, the determination is often ill-suited for decision as a matter of law, on a motion to dismiss, for the "determination 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, and these assessments are peculiarly ones for the trier of fact." *TSC*, 426 U.S. at 450; *accord Provenz v. Miller*, 102 F.3d 1478, 1489 (9th Cir. 1996); *Am. West*, 320 F.3d at 934; *Asher v. Baxter Int'l*, 377 F.3d 727, 735 (7th Cir. 2004) (Easterbrook, J.) ("inappropriate to entertain" defendants' immateriality argument at the pleading stage), *cert. denied*, 544 U.S. 920 (2005).

The district court's "statistical significance" criterion for materiality contradicted these precedents. It erected an artificial, bright-line test that ignored the complex factual inquiries inherent in any valid materiality analysis. "Any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be over- or underinclusive."

Basic, 485 U.S. at 236; *Am. West*, 320 F.3d at 934 ("we decline to adopt a bright-line rule" for materiality); *Ganino*, 228 F.3d at 162 ("ample authority" for position that exclusive reliance "on a single numerical or percentage benchmark to determine materiality was error").

2. The District Court Misunderstood – and Then Misapplied – the Concept of "Statistical Significance"

The district court depended heavily upon the Second Circuit case of *Carter-Wallace II* to support its central theme that unless a "statistically significant" number of adverse reports were communicated to defendants, the undisclosed information was immaterial as a matter of law. ER88:8-12.

Carter-Wallace was a securities-fraud action involving a pharmaceutical company and its epilepsy drug Felbatol. *Carter-Wallace II*, 220 F.3d 36; *Carter-Wallace I*, 150 F.3d 153. Plaintiffs there alleged that defendants' awareness, over a period of 10 months, of some 57 "adverse medical reports" concerning Felbatol users had triggered the company's duty to disclose those reports to investors. *Carter-Wallace II*, 220 F.3d at 38.

The Second Circuit disagreed, explaining that most of the adverse reports were ***unrelated to Felbatol use***, and thus not "statistically significant." *Id*. at 41. Only 6 of the 57 reports concerned "aplastic anemia," a frequently fatal form of acquired bone marrow failure. *Id*. at 38. "The other illnesses, although serious and even fatal in some instances, ***were never linked*** to Felbatol." *Id*. at 41 (emphasis added). Once

Carter-Wallace had received four additional reports of aplastic anemia deemed related to Felbatol, however, the number of adverse incidents – a total of ten – ***had*** risen to what the panel deemed a statistically significant level. *Id*. at 40-42. It was on that date, held the Second Circuit, that the company "acted reasonably once the linkage was established between aplastic anemia and Felbatol." *Id*. at 42.

Although, like *Carter-Wallace II*, the district court here repeatedly used the term "statistical significance" to denote what it believed to be a sufficiently high number of anosmia complaints, the term actually has a quite different meaning. Statistical significance is "a technical term that ***concerns only*** whether an observed relationship is real or is the product of chance variation or the effect of an intervening variable." Melvin Aron Eisenberg, *Bad Arguments in Corporate Law*, 78 Geo. L.J. 1551, 1555 (1990) (emphasis added). In other words, statistical significance "means that an observed difference cannot be attributed to chance alone, that something besides random error is afoot." Jack F. Williams, *Distrust: The Rhetoric and Reality of Means-Testing*, 7 Am. Bankr. Inst. L. Rev. 105, 131 n.105 (1999).[15]

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[15] *See also* online encyclopedia Wikipedia, at http://en.wikipedia.org/wiki/Statistical_significance (an observed result is said to be "significant if it is unlikely to have occurred by chance"); *accord* Web site of "StatPac" survey software, at http://www.statpac.com/surveys/statistical-significance.htm (when a statistic is deemed "significant, it simply means that you are very sure that the statistic is reliable").

A true application of statistical significance to this case by the district court would have required a formal study to assess whether the observed phenomena at its heart – the numerous cases of anosmia following Zicam use – were something other than purely random events. Valid assessments of statistical significance "can only come from formal trials or studies." Sarah M.R. Cravens, *The Usage and Meaning of "Clinical Significance" in Drug-Related Litigation*, 59 Wash & Lee L. Rev. 553, 580-81 (2002).[16] Dependable conclusions do not result from a court plucking some arbitrary number of complaints from thin air. Indeed, even a trained professional's own experience and expertise observing individuals and groups is no substitute for formal trials. *Id*. at 580. In those trials, sample sizes, "p-values," and "null hypotheses" must all be taken into account. *See, e.g.*, *Confronting the New Challenges of Scientific Evidence*, 108 Harv. L. Rev. 1481, 1540-41 (1995).

The district court considered none of this, however. It simply made its confident proclamation that the number of Zicam-using anosmia sufferers was not

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[16] *See also* http://www.statpac.com/surveys/statistical-significance.htm ("Whenever we perform a significance test, it involves comparing a test value that we have calculated to some critical value for the statistic.").

statistically significant as a matter of law. ER88:8-12. That holding was insupportable, for the court never conducted a test of statistical significance.[17]

Even if the district court had somehow correctly divined that the 20-plus reported cases of Zicam-induced anosmia known to defendants during the Class Period (*see* p. 51, *infra*) would be statistically ***in***significant in a valid formal trial, that still would not mean that they were irrelevant to defendants' knowledge. Statistically significant differences "may or may not be ***practically or legally significant***." Williams, *supra*, 7 Am. Bankr. Inst. L. Rev. at 131 n.105 (emphasis in original); *see also* Richard Lempert, Symposium on Law and Economics: *Statistics in the Courtroom: Building on Rubinfeld*, 85 Colum. L. Rev. 1098, 1099 (1985) ("Statistical significance and substantive significance do not necessarily coincide; the likelihood of a statistically significant relationship varies both with sample size and the appropriateness of the statistical procedures.").

After all, the standard of proof in this civil action is a simple preponderance of the evidence – and "[w]hether a correlation between a cause and a group of effects is more likely than not – particularly in a legal sense – is a different question from that answered by tests of statistical significance, which often distinguish narrow

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[17] Interestingly, the court never stated how many adverse reports to Matrixx it thought ***would*** be statistically significant – just that the ones alleged were not enough.

differences in degree of probability." *Allen v. United States*, 588 F. Supp. 247, 417 (D. Utah 1984), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987).[18] "Failure to show that a disparity or association is statistically significant . . . means only that the null hypothesis cannot be rejected, not that it is true." *Confronting the New Challenges of Scientific Evidence*, *supra*, 108 Harv. L. Rev. at 1543-44; *see also Allen*, 588 F. Supp. at 417 ("The cold statement that a given relationship is not 'statistically significant' cannot be read to mean 'there is no probability of a relationship.'").

In the case at bar, a valid assessment of "statistical significance" would have estimated the probability that the myriad reports of anosmia in the Zicam-using population were either utterly random events (the "null hypothesis"), or in fact perhaps linked to the intranasal Zicam. Whether or not the number of anosmia complaints received by the Matrixx defendants rose to a level requiring truthful disclosures in their public statements presents a clear question of fact. *E.g.*, *Green Tree*, 270 F.3d at 666 ("Whether defendants could have believed during the class period that the reserves were an adequate response is a question of fact that cannot

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[18] *See also* Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 686, 696-97 (1992) ("Peremptorily rejecting all studies that are not statistically significant would be a cursory and foolish judgment, particularly if there are multiple studies tending to show a consistent effect.").

render the complaints inadequate, lest the heightened pleading requirements of the Reform Act replace the function of a trial.").

It was a question ill-suited for the district court to decide, as a matter of law, in the absence of a rigorous assessment of statistical significance.

3. Even Assuming *Arguendo* that the Second Circuit's Requirement of "Statistical Significance" Was Proper, the District Court Misread *Carter-Wallace II*'s Conclusion – for the Opinion's Result Actually Supports Plaintiffs Here

Based on the foregoing, the district court's reliance on what it considered "statistical significance" cannot be justified. Nor can the Second Circuit's panel in the *Carter-Wallace* decisions – for that panel made the same mistake as the district court here, in announcing a "statistically significant" benchmark without doing a proper statistical analysis first. But even if this Court were to accept the Second Circuit's abbreviated discussion of "statistical significance" in *Carter-Wallace I* and *II*, that lawsuit's facts and that panel's reasoning end up supporting plaintiffs here. The district court ruled otherwise because it misread the opinion.[19]

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[19] Although the district court relied mainly upon the *Carter-Wallace II* panel's view of "statistical significance" to hold the numerous, adverse reports here immaterial, it also cited some other decisions that it said followed *Carter-Wallace II*'s "reasoning." ER88:9-10. Each is readily distinguishable. The Third Circuit in *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000), found allegedly adverse reports immaterial because, *inter alia*, the company's stock price did not react to their disclosure. *Id*. at 283. This Court has expressly rejected *Oran*'s reasoning on the point, however. *See*

As noted *supra*, the Second Circuit held that it was not until one specific point was reached in the summer of 1994 that a series of seemingly random adverse events associated with the Felbatol drug coalesced into an actual link showing defendants' knowledge. *Carter-Wallace II*, 220 F.3d at 40-41. In July 1994 Carter-Wallace "received four additional reports of aplastic anemia" (*id*. at 38) – bringing to ***ten*** the total number of aplastic anemia reports known to defendants. *Id*.; *see also Carter-Wallace I*, 150 F.3d at 155 ("On August 1, 1994, after four additional deaths were reported in July – amounting to a total of ten deaths – Carter-Wallace and the FDA

Am. West, 320 F.3d at 934 ("Defendants urge us to adopt [*Oran*'s] per se rule . . . . However, we decline to do so because adoption of such a rule would contravene" the Supreme Court's holdings in *Basic* and *TSC*.). Although the court in *In re Alliance Pharm. Corp. Sec. Litig.*, 279 F. Supp. 2d 171, 189 (S.D.N.Y. 2003), said that *Carter-Wallace II* "implicitly recognized" that not every adverse effect in a clinical trial is automatically material, plaintiffs here never suggested any such bright-line rule. Moreover, the *Alliance* defendants made ***no*** statements of the results or progress of a clinical trial, other than to note truthfully that the drug in question was still being evaluated. *Id*. That circumspection was not present here, where defendants insisted that any talk of a link between Zicam and anosmia was completely unfounded, that Zicam's safety and efficacy were well-established, and strongly implied that Matrixx had conducted two trials testing for anosmia. The remaining decisions, both unpublished, are similarly inapposite to the court's materiality holding here. *See In re Bayer AG Sec. Litig.*, No. 03 Civ. 1546 (WHP), 2004 U.S. Dist. LEXIS 19593, at *29 (S.D.N.Y. Sept. 30, 2004) (acknowledging that even under *Carter-Wallace II*, when adverse reports are sufficiently serious and frequent as to affect future earnings, companies ***are*** obligated to disclose them); *see also Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 U.S. Dist. LEXIS 22858 (N.D. Cal. Sept. 18, 1996) (plaintiffs conceded that defendants' summaries of drug study were factually accurate; defendants under no obligation to second-guess the study's methodology).

issued a 'Dear Doctors' letter, recommending most patients be withdrawn from Felbatol treatment."). It was at that point, said the Second Circuit, that the number of adverse events ***had*** become statistically significant. *Carter-Wallace I*, 150 F.3d at 157; *Carter-Wallace II*, 220 F.3d at 40 ("Our determination [in *Carter-Wallace I*] that the reports of aplastic anemia were not statistically significant prior to August 1, 1994 is the law of this case . . . ."); *id*. at 41 ("it was not reckless for Carter-Wallace to believe that these reports were random and statistically insignificant before August 1, 1994").

Under that reasoning, then, the facts here satisfy even the *Carter-Wallace* "statistical significance" benchmark – for this Complaint details ***more than twice*** the number of specifically linked adverse events than the ten alleged in *Carter-Wallace*.

The math is straightforward. There were the ten anosmia cases detailed in the September 2003 Jafek-Linschoten-Murrow poster presentation, of course. ER68:¶28. But there also many others: The "cluster" of cases observed by Dr. Hirsch since 1999, with "at least one" described to Matrixx in December 1999 (ER68:¶25); the "several patients" Dr. Linschoten had treated at the RMTSC, among whose ranks was one patient who had also complained to Matrixx (and who had prompted defendant Clarot's September 2002 phone call to Dr. Linschoten) (ER68:¶26); the "other customers" whom Clarot conceded had been complaining to Matrixx "as early as 1999" (*id*.); and the nine plaintiffs in the four product liability lawsuits filed before

and during the Class Period (ER68:¶49). Even under the most conservative tabulation of these various injured consumers, the number of Zicam-anosmia complaints communicated to Matrixx prior to and during the Class Period adds up to ***at least 23***. Surely there arises an inference that the actual numbers were even higher than those 23.[20]

Other parts of *Carter-Wallace II* favor plaintiffs here as well. The other, 40-plus adverse reports communicated to the Carter-Wallace company did not trigger any knowledge on defendants' part because they were so random and apparently unrelated to the suspect drug Felbatol; under FDA rules, reports of adverse events had to be made "'***whether or not considered drug related***.'" 220 F.3d at 41 (citation omitted; court's emphasis). Carter-Wallace thus received adverse reports whenever Felbatol users became ill, "regardless of whether or not the illness had anything to do with Felbatol." *Id*. Here, in contrast, the alarming reports were of a singular reaction – loss

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

of sense of smell immediately following Zicam application into the nose – that the complainants and researchers each attributed ***specifically*** to the product.

And, while *Carter-Wallace II* cautioned that drug companies "'need not disclose isolated reports'" of adverse events, it also acknowledged that the companies must disclose them once the reports "'are sufficiently serious and frequent to affect future earnings.'" 220 F.3d at 40 (quoting *Carter-Wallace I*, 150 F.3d at 157). Given that just 10 adverse reports there satisfied that criterion, *id*. at 41-42, surely the 23 reports here did. Indeed, the Matrixx defendants themselves warned investors that ***just one*** product liability suit – even if lacking merit – "could materially adversely affect our results of operations and financial condition." ER68:¶35. Imagine what 23 such suits, each of them complaining of Zicam-induced loss of sense of smell, potentially meant for Matrixx's earnings prospects! Surely that is the sort of material information that mattered to reasonable investors. *TSC*, 426 U.S. at 449.

Given the foregoing, the district court's conclusion that "[s]imilar to *Carter-Wallace*, Plaintiffs present minimal evidence of Zicam complaints" (ER88:11), cannot be squared with either that decision or the Complaint's detailed allegations. The numerous complaints of which defendants were concededly aware are significant enough to at least preclude a finding of immateriality as a matter of law.

VIII. CONCLUSION

For the foregoing reasons, the decision below must be reversed.[21]

DATED: August 7, 2006

Respectfully submitted,

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[21] The district court never addressed plaintiffs' §20(a) "control-person" claims against CEO Johnson and CFO Hemelt, but presumably would have dismissed them because it held there was no viable Exchange Act claim. Plaintiffs pleaded the duo's control-person status, ER68:¶¶82-85, however, and to the extent this Court reverses the district court's dismissal, plaintiffs' §20(a) claims remain viable.

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RULE 28-2.6 STATEMENT OF RELATED CASE

Plaintiffs-Appellants are unaware of any related cases.

CERTIFICATE OF COMPLIANCE

The undersigned counsel certified that Plaintiffs-Appellants' Opening Brief uses a proportionally spaced Times New Roman typeface, 14-point, and that the text of the brief comprises 12,488 words according to the word count provided by Microsoft Word 2002 word processing software.

JOSEPH D. DALEY

DECLARATION OF SERVICE BY MAIL

I, the undersigned, declare:

1. That declarant is and was, at all times herein mentioned, a citizen of the United States and a resident of the County of San Diego, over the age of 18 years, and not a party to or interested party in the within action; that declarant's business address is 655 West Broadway, Suite 1900, San Diego, California 92101.

2. That on August 7, 2006, declarant served **PLAINTIFFS-APPELLANTS' OPENING BRIEF** by depositing 2 true copies thereof in a United States mailbox at San Diego, California in a sealed envelope with postage thereon fully prepaid and addressed to the parties listed on the attached Service List.

3. On the same date, declarant filed one original and 15 copies of **PLAINTIFFS-APPELLANTS' OPENING BRIEF** with the Clerk of the Court by depositing in a United States mailbox at San Diego, California in a sealed package with postage thereon fully prepaid.

4. That there is a regular communication by mail between the place of mailing and the places so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 7th day of August, 2006, at San Diego, California.

TAMARA THWEATT