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' REPLY BRIEF

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
WILLIAM S. LERACH
DARREN J. ROBBINS
JOSEPH D. DALEY
SCOTT H. SAHAM
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
SAMUEL H. RUDMAN
DAVID A. ROSENFELD
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

Attorneys for Plaintiffs-Appellants
[Additional counsel appear on signature page.]

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A. The District Court's Improper Construction of a Bright-Line Materiality Test Requiring "Statistical Significance" Warrants Reversal

1. Defendants Vainly Attempt to Downplay the District Court's Insistence on "Statistical Significance" as a Litmus Test for Materiality

This appeal concerns the district court's construction of an artificial, bright-line test for materiality at the motion-to-dismiss stage. On no fewer than ten instances in its Order dismissing the Complaint did the district court mention the concept of "statistical significance." Repeatedly, the court pronounced plaintiffs' allegations immaterial ***as a matter of law*** because they did not comprise evidence of what it considered "statistically significant" events. *See, e.g.*, ER88:11 ("the Court finds 12 user complaints is not statistically significant"); ER88:12 ("the Court finds that . . . Plaintiffs have failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia").

Despite those demands for statistically significant evidence, defendants insist that the district court's materiality analysis was much more benign. They accuse plaintiffs of "[a]ttempting to manufacture a flaw" in the court's reasoning, and of "elevat[ing] the district court's statements about statistical significance beyond their import." Defendants' Answering Brief ("Defs.' Brf.") at 35.

But any reasoned review of the court's order reveals that "statistical significance" is precisely what drove the court's analysis. Indeed, the court even allowed its bright-line test to overpower the traditionally liberal context of leave to amend. It warned plaintiffs that any amendment would be futile, unless plaintiffs satisfied its requirement of statistically significant evidence: "Absent allegations Defendants ***knew*** there was a definitive and statistically significant link between Zicam and anosmia . . . , any amendment would be futile." ER88:14 (court's emphasis). This directive contradicted the traditional liberality associated with leave-to-amend considerations. *See* Fed. R. Civ. P. 15; *see also Foman v. Davis*, 371 U.S. 178, 182 (1962); *Eminence Capital, L.L.C. v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

The district court's materiality analysis was flawed – and the Supreme Court says so. "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 Inc. v. Levinson*, 485 U.S. 224, 236 (1988). This Court agrees. *See No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.* ("*Am. West*"), 320 F.3d 920, 934 (9th Cir.

2003) ("we decline to adopt a bright-line rule" for materiality). The precedents are in accord.[1]

Thus, a correct analysis of materiality here asks not whether some artificial benchmark was reached, but only whether "'a reasonable shareholder would consider it important'" that large numbers of Zicam users had lost their sense of smell, or whether that fact "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)); *Am. West*, 320 F.3d at 934.

Incredibly, defendants ***do not even acknowledge*** *Basic*'s existence! Similarly, while they cite elsewhere this Court's *Am. West* opinion for a portion of its scienter discussion, they ignore entirely its materiality holding that "we reject Defendants' argument for adoption of a bright-line rule . . . and, instead, engage in the 'fact-specific inquiry' set forth in *Basic*." *Am. West*, 320 F.3d at 934 (citing *Basic*, 485 U.S. at 240).

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[1] *See, e.g.*, *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (there is "ample authority" for position that exclusive reliance "on a single numerical or percentage benchmark to determine materiality was error"); *Martinez v. Schlumberger, Ltd.*, 338 F.3d 407, 428 (5th Cir. 2003) (rejecting "bright-line" approach to materiality).

Ignoring the relevant precedents allows defendants to construct their own materiality test that is simply another way of demanding the "statistical significance" the district court improperly sought. Repeatedly, they carp that the Complaint alleges only a "limited" number of "isolated" complaints concerning Zicam-linked anosmia. *See, e.g.*, Defs.' Brf. at 3 ("limited number of complaints"); *id*. at 9 (user complaints "were limited and sporadic"); *id*. at 16 ("limited number of user complaints"); *id*. ("small number of user complaints"); *id*. at 28 ("isolated user complaints"). Defendants' insistence that the dramatic complaints were immaterial because they were ostensibly "isolated" is wrong on two levels.

First, defendants engage in classic question-begging by assuming, in the first place, that the numerous complaints communicated to them were somehow "isolated" or "limited."[2] Their self-serving characterization of the numbers' significance cannot control – especially on a motion to dismiss. In common parlance, "isolated" means "solitary," or "alone"[3] – and surely the nearly ***two dozen*** adverse reports

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[2] Begging the question is the fallacy of assuming the truth of the very thing being questioned. *See, e.g.*, Aristotle, *Prior Analytics* (Book II) 16 (350 B.C.) (translation by A. J. Jenkinson) ("whenever a man tries to prove what is not self-evident by means of itself, then he begs the original question").

[3] *See The American Heritage Dictionary* 680 (2d ed. 1985).

conservatively alleged here were anything but that.[4] The personal-injury plaintiffs who filed suit against Matrixx before the Class Period's end were scattered across the nation. ER68:¶49. Their numbers were complemented by the ten patients who were studied by Dr. Bruce Jafek and his colleagues at the University of Colorado School of Medicine. ER68:¶28. Defendant Clarot contacted Dr. Miriam Linschoten in September 2002 and admitted that (a) one of her patients had also complained to Matrixx about Zicam causing a lost sense of smell, and (b) there were ***other Zicam users*** who had similarly complained to Matrixx as far back as three years earlier. ER68:¶26. Defendants may try to put a benign label on the phenomenon, but the fact remains that two dozen complaints of a horrific, life-altering reaction to a drug are anything but "isolated" or "limited."[5]

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[4] Defendants question plaintiffs' "creative math" in tabulating at least 23 complaints, versus the 12 cited by the district court. Defs.' Brf. at 31 n.13. Plaintiffs stand by their conservative calculations, and urge this Court to re-read the text at p. 51 and n.20 of plaintiffs' Opening Brief ("Pltfs.' Brf."). That text explains that while hundreds of Zicam users eventually filed suit against Matrixx, ***at least 23*** complaints had to have been known to defendants before then – more than twice the number of adverse reports deemed "statistically significant" by *In re Carter-Wallace Sec. Litig.* ("*Carter-Wallace II*"), 220 F.3d 36 (2d Cir. 2000).

[5] Defendants argue that the Complaint "makes no such claim" that Zicam was ***causing*** users to lose their sense of smell. Defs.' Brf. at 29. Even a cursory look at the Complaint illustrates that they are mistaken. *See* ER68:¶¶5-6, 8, 28, 30, 48-49.

Second, putting aside the fallacy that two dozen complaints of lost sense of smell are so "limited" as to be immaterial as a matter of law, defendants' own filing with the Securities and Exchange Commission ("SEC") concedes how material ***just one*** such complaint could be, both to Matrixx and to its investors:

> 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. Surely, if just one claim could have a materially negative effect upon Matrixx's bottom line, the fact that there existed two dozen known consumers complaining of Zicam-induced anosmia – of which ***nine had filed lawsuits*** during the Class Period – ratcheted up the "materiality" of the information coming into Matrixx's executive suites. And, just as surely, Matrixx investors would have considered it important that numerous Zicam users were complaining of Zicam-induced anosmia. *See Basic*, 485 U.S. at 240 ("As we clarify today, materiality depends upon the significance the reasonable investor would place on the withheld or misrepresented information."); *accord TSC*, 426 U.S. at 449. Thus, "a complaint may not properly be dismissed pursuant to Rule 12(b)(6) . . . on the ground that the alleged misstatements or omissions are not material ***unless they are so obviously unimportant*** to a reasonable investor that reasonable minds could not differ on the question of their

importance." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985) (emphasis added).

Defendants' SEC filing also eviscerates their argument that the four Class-Period lawsuits are irrelevant because the Complaint fails to allege the amount of damages at issue, or Matrixx's potential exposure compared to its revenues. Defs.' Brf. at 39. As a threshold matter, it is reasonable to credit the inference in plaintiffs' favor that numerous product-liability lawsuits alleging ***lost sense of smell*** would not seek a pittance from the Company. Moreover, defendants themselves warned their shareholders that just one suit could have major, negative impacts on Matrixx's fortunes. ER68:¶35. On a related note, defendants also chide plaintiffs for not alleging the "merit" of the two-plaintiff *Christensen* lawsuit that they did not timely disclose (Defs.' Brf. at 41) – but again, it was defendants themselves who conceded that the merits of product-liability suits directed at Matrixx had nothing to do with their materiality. ER68:¶35.[6]

Finally, defendants have no persuasive response to the argument in plaintiffs' Opening Brief that the *Carter-Wallace* opinions actually ***support*** materiality here. *See*

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[6] This admission renders inapposite defendants' reliance on *City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245 (10th Cir. 2001), where the plaintiffs had not alleged facts showing that an undisclosed litigation risk was material to the company. *Id*. at 1264-65.

Pltfs.' Brf. at 48-52. Recall, the Second Circuit held that although a series of seemingly random drug-reaction reports triggered no duty of disclosure, there came a point when the reports coalesced into an actual link showing defendants' knowledge. *Carter-Wallace II*, 220 F.3d at 40-41. It was when the number of reports linking the drug with a specific reaction reached a total of ten, said that court, that the number of adverse events ***had*** become statistically significant. *In re Carter-Wallace, Inc.* ("*Carter-Wallace I*"), 150 F.3d 153, 157 (2d Cir. 1998); *Carter-Wallace II*, 220 F.3d at 40. It was at that point that the drug company "had reason to believe that the commercial viability of [the drug] was threatened." *Carter-Wallace I*, 150 F.3d at 157; *accord Carter-Wallace II*, 220 F.3d at 40. Under that analysis, plaintiffs here easily alleged a statistically significant number of reports.

Defendants respond with a half-hearted swipe at plaintiffs' calculations, preferring the district court's (erroneous) count of just "12" Zicam user complaints versus the more-accurate 23 or so tabulated in the Complaint. *See* ER68:¶¶25-26, 28, 49; *see also* Pltfs.' Brf. at 51. As already shown *supra* in n.4, however, defendants' mathematical quibbling is without merit.

Defendants are left insisting that whatever the actual number of complaints, there simply was no established causal link between Zicam and anosmia. *E.g.*, Defs.' Brf. at 31 ("unsubstantiated"); *id*. at 35 (questioning the "reliability and accuracy of the user complaints"). There was, defendants assert, "no clinical study ***or other***

research [that] established a causal relationship" between the two. Defs.' Brf. at 30 (emphasis added).

Defendants are wrong three times over.

First, they seem to forget that this case is at the motion-to-dismiss stage. The Complaint's allegations do not have to "establish" or prove ***anything*** at this point in the litigation. It is enough that plaintiffs have alleged that Zicam was being linked with a horrific side effect by both medical researchers and Zicam users, with the link communicated to defendants; those allegations must be accepted as true. *Am. West*, 320 F.3d at 925 n.2. Despite the heightened pleading burden plaintiffs face under the Private Securities Litigation Reform Act ("PSLRA"), that has not altered the bedrock principle that the motion-to-dismiss stage is not to be turned into a mini-trial. *Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 666 (8th Cir. 2001) (questions of fact not appropriately decided at motion-to-dismiss stage, "lest the heightened pleading requirements of the Reform Act replace the function of a trial"); *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1101 (10th Cir. 2003) ("The PSLRA did not, however, purport to move up the trial to the pleading stage."); *Am. West*, 320 F.3d at 946 ("we are cautious to raise the bar of the PSLRA any higher than that which is required under its mandates . . . [a] failure to accept Plaintiffs' allegations as true and construe them in the light most favorable to Plaintiffs does just that").

Second, defendants have no business importing a subjective "reliability" criterion into this, a ***materiality*** inquiry. *Goldman*, 754 F.2d at 1067 ("Even if the court itself had felt" that alleged adverse reports "were clearly ***not*** problems," it could not properly determine as a matter of law whether the undisclosed facts would be important to a reasonable investor.) (court's emphasis). The only question is whether there existed a substantial likelihood that a reasonable Matrixx shareholder would have wanted to know that Matrixx's core product had been linked by researchers and the product's users to a horrific physiological response. *TSC*, 426 U.S. at 449. Surely one would.

Finally, the record belies defendants' "no research" swipe. The Complaint alleges that "***researchers***" in the Department of Otolaryngology at the University of Colorado School of Medicine, The Rocky Mountain Taste and Smell Center, and the Smell & Taste Treatment and Research Foundation Ltd. had observed numerous cases of anosmia following Zicam use. ER68:¶24 (emphasis added). The RMTSC was a "***collaborative research effort***" by the University of Colorado School of Medicine's "Cellular & Structural Biology" and Otolaryngology departments. *Id*. at n.1 (emphasis added). The Complaint further specified that as of September 2003, the University of Colorado's Dr. Bruce Jafek "had observed 10 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 (ER68:¶64)), Dr. Jafek submitted the trio's Zicam-anosmia findings to the American Rhinologic Society in September 2003. ER68:¶28. Their "***research*** provided a detailed description" of one 55-year-old subject. *Id.* (emphasis added). In addition to his detailed case study, "the University of Colorado ***researchers*** reported" on other Zicam users with similar symptoms. *Id*. (emphasis added). Given the foregoing, the Complaint's allegations that researchers believed there was a causal link between Zicam and anosmia in numerous individuals must be credited.

Defendants invite this Court to join them in questioning the quality and reliability of that research, but such skepticism would be improper. *E.g.*, *Neitzke v. Williams*, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations"); *Goldman*, 754 F.2d at 1067 ("court's function on a Rule 12(b)(6) motion is not to weigh the evidence that might be presented at a trial"). Moreover, defendants offer nothing concrete to cast doubt on the legitimacy of the University of Colorado researchers, the American Rhinologic Society, or the *American Journal of Rhinology* in which the researchers' findings were published.

Nor can they. For example, there is nothing in the record suggesting that any of the Jafek-Linschoten-Murrow study authors were not respected members in their field of discipline. Indeed, defendants overlook that co-defendant Clarot, Matrixx's Vice President of Research and Development, reached out to Dr. Linschoten ***a year prior*** to

the American Rhinologic Society presentation, and ***invited her to participate*** in further studies. ER68:¶¶26-27.

The trio presented their Zicam-anosmia paper in front of the American Rhinologic Society in September 2003. Again, there is no suggestion in the record that the Society is anything but a respected medical association.[7] Defendants certainly took the Society and the poster presentation seriously: When Matrixx later convened a two-day meeting of "physicians and scientists to review current information on smell disorders" ***they conceded it was in response to*** "a poster presentation at the American Rhinological [sic] Society in September 2003." ER68:¶45.

Later, 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. Although the Complaint does not allude to the fact, the *American Journal of Rhinology* publishes

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[7] The American Rhinologic Society's Web site notes that it "is the world's largest physician organization whose mission focuses upon the medical and surgical treatment of patients with diseases of the nose and paranasal sinuses. Patient care, research and education are integral to the ARS mission." *See* http://www.american-rhinologic.org/.

"peer-reviewed" materials.[8] The record reflects, however, that the "same research" from the Jafek-Linschoten-Murrow study, presented to the American Rhinologic Society in September 2003, ***is the very same research*** that "was ultimately subjected to peer review, passed peer review and was published" in the *American Journal of Rhinology*. Transcript at 35:18-36:12.

Given the foregoing, defendants' attempts to muddy the Zicam-and-anosmia information coming into Matrixx as somehow "unreliable" or "unresearched" falls flat.[9] The Complaint's allegations must be credited.

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[8] 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. It is the "official journal of the American Rhinologic Society," which considers it the "premier journal dedicated to nasal and sinus disease." *See* http://www.american-rhinologic.org/journal.phtml.

[9] Defendants also attempt to manufacture a dispositive difference between the zinc "gluconate" that Zicam contains, and the zinc "sulfate" that was used in some older studies that Dr. Linschoten told defendant Clarot about in 2002. Defs.' Brf. at 30 n.12, 52. That alleged difference is actually a bit of misdirection, however. The Complaint alleges that "zinc," ***period***, was known to be toxic and cause anosmia. *See* ER68:¶25 ("intranasal application of zinc"); ER68:¶27 ("[z]inc's toxicity" confirmed by studies dating to 1930s); ER68:¶30 (researchers' peer-reviewed article explains that "[z]inc ions are toxic to olfactory epithelium"). In any event, even if Dr. Linschoten had never mentioned the zinc sulfate studies to Matrixx, defendants had received plenty of warnings during the Class Period that ***zinc gluconate*** was causing anosmia. ER68:¶¶24-26, 28, 49.

2. On the Facts Presented, Materiality Is Better Left for a Trier of Fact

Materiality is ordinarily ill-suited for decision as a matter of law, 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 Am. West*, 320 F.3d at 934; *Provenz v. Miller*, 102 F.3d 1478, 1489 (9th Cir. 1996); *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 735 (7th Cir. 2004) (Easterbrook, J.) ("inappropriate to entertain" defendants' immateriality argument at the pleading stage), *cert. denied*, 544 U.S. 920 (2005); *Pirraglia v. Novell, Inc.*, 339 F.3d 1182, 1192 n.13 (10th Cir. 2003) ("This issue is not ripe for resolution at the Rule 12(b)(6) stage.").[10] Whether the undisclosed, numerous reports 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.

In response, defendants say that materiality determinations "often [are] made – as a matter of law" at the motion-to-dismiss stage, citing just three opinions in support. Defs.' Brf. at 29. The trio of decisions is unpersuasive, however. *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000), decided materiality as a matter of law, true –

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[10] Plaintiffs acknowledge that, on rare occasions, materiality may be decided as a matter of law.

but this Court has specifically rejected *Oran*'s use of a bright-line materiality test! *See 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*.). Similarly, *Carter-Wallace I* used the same flawed, bright-line "statistical significance" test at issue on this appeal. Defendants' third case, an unpublished district court decision, is inapposite on at least three levels: (1) it relies upon the (rejected) *Oran* and (questionable) *Carter-Wallace I* decision, (2) it employs a bright-line "statistical significance" test for materiality, and (3) it never even mentions this Court's *Am. West* opinion rejecting bright-line materiality tests. *See In re Intrabiotics Pharms. Sec. Litig.*, No. C 04-02675 JSW, 2006 U.S. Dist. LEXIS 56427 (N.D. Cal. Aug. 1, 2006).[11]

3. Defendants' Alternative Grounds for Affirmance Are Unavailing

Perhaps sensing the shaky "materiality" ground upon which they stand, defendants urge this Court to affirm the district court's dismissal on other grounds. Defs.' Brf. at 25-26. They say that the Complaint does not allege their misstatements with particularity, that certain of their statements were merely inactionable "puffing"

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[11] In addition, even assuming that the negative reports at issue in *Intrabiotics* were material, the plaintiffs had failed to allege that defendants received the reports before making misstatements. *Id*. at *43.

and vague opinions, and that plaintiffs have not alleged which specific defendant made which particular misstatement. *Id.* at 22-26. Their suggested affirmance on these grounds not reached by the district court should be rejected, for two reasons.

First, appellate courts ordinarily decline to reach issues that were not actually reached and decided by the district court.[12] Reaching such grounds is particularly inappropriate where the decision below was rendered on a question of law at a preliminary stage of the litigation.

In addition, none of the alternative grounds suggested – lack of particularized pleadings, "puffery," and a failure to identify "speakers" – is a valid one.

The Complaint plainly sets forth the three categories of false and misleading statements, and explains why they were false. First, defendants had reassured investors that Zicam was an efficacious product that would drive the momentum of Matrixx's rising revenues. ER68:¶¶32-34, 37. This reassurance was false, as

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[12] *See United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1022 (9th Cir. 2006) ("while 'we ***may*** affirm the district court's judgment on a different ground, we need not do so,' and 'we usually do not'") (emphasis in original, citation omitted); *Andersen v. Cumming*, 827 F.2d 1303, 1305 (9th Cir. 1987) ("[o]rdinarily we will not decide an issue that was not addressed by the district court") (citing *Greater Los Angeles Council on Deafness v. Zolin*, 812 F.2d 1103, 1107 (9th Cir. 1987)); *Desi's Pizza, Inc. v. City of Wilkes-Barre*, 321 F.3d 411, 428 (3d Cir. 2003) (declining to consider proposed alternative ground for affirmance: "we 'generally decline to address issues that have not been passed upon below absent exceptional circumstances'") (quoting *Equibank, N.A. v. Wheeling-Pittsburgh Steel Corp.*, 884 F.2d 80, 86 (3d Cir. 1989)).

"numerous users of the Zicam product had suffered a complete loss of [sense of] smell," and researchers at the University of Colorado "had linked Zicam and its operative ingredient to anosmia." ER68:¶32. Similarly, because defendants knew that Zicam was causing some users to lose their sense of smell, Matrixx's top executives could ***not*** have been "extremely encouraged" or realistically claimed "very strong momentum" heading into cold-and-cough season. ER68:¶33; *Fecht v. Price Co.*, 70 F.3d 1078, 1083 (9th Cir. 1995) ("allegations of specific problems undermining a defendant's optimistic claims suffice to explain ***how*** the claims are false") (Court's emphasis).

Second, defendants claimed that ***if*** product-liability claims ***were*** to arise from use of a Matrixx product, serious financial consequences ***could*** follow. ER68:¶35. That statement was misleading, for it omitted that defendants had ***already*** been sued by two plaintiffs in the *Christensen* litigation the month before – and, given the findings of the University of Colorado researchers, additional suits were likely. ER68:¶¶35, 49. "'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)). Defendants should have disclosed the charges leveled against Zicam by

the two *Christensen* plaintiffs, as well the ten user complaints compiled by the University of Colorado researchers.

Finally, in response to a January 30, 2004, *Dow Jones Newswires* report concerning complaints about Zicam-induced anosmia, defendants issued a press release claiming that the complaints 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, 41. The Complaint specifies that "[s]uch statements were materially false and misleading because, as the Company would later admit, no clinical study" had been held to examine such a relationship, "and other research had, in fact, shown such a link." ER68:¶41; *see also* ER68:¶47 (media reporting "stunning information" that "makers of the nationally advertised cold remedy Zicam now admit that they don't know if their nasal gel could cause loss of smell"). Moreover, the statements failed to disclose the research conducted at the University of Colorado, linking Zicam to anosmia. ER68:¶39(e). Plaintiffs have set out each false statement and described the specifics undermining the statement's truthfulness. *Cooper v. Pickett*, 137 F.3d 616, 626 (9th Cir. 1998); *Fecht*, 70 F.3d at 1083.

Nor are the false statements so easily brushed aside as mere "puffery" or vague opinion. For one thing, even general expressions of optimism may be actionable under the federal securities laws. *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 501 (9th Cir. 1992); *United States v. Smith*, 155 F.3d 1051, 1064 n.22 (9th Cir. 1998)

("there simply is no per se rule that 'soft' information cannot be 'material' within the meaning of Rule 10b-5"). "What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989).

Moreover, defendants made specific, pointed reassurances about the Company's ***core*** performer. ER68:¶2. Investors would be hungry for such reassurances, because the information came from the Company's top executives – and this Court recognizes that investors "'justifiably place[] heavy reliance on the statements and opinions of corporate insiders.'" *Hanon*, 976 F.2d at 503 (citation omitted).

Thus, Matrixx investors undoubtedly listened when defendants assured them that the Zicam brand was an "efficacious product." ER68:¶32. But how could a product that was allegedly destroying some users' sense of smell be considered "efficacious" at the same time? Defendants asserted that Zicam was ***the*** driving force behind Matrixx's "very strong momentum" heading into cough-and-cold season, by offering a "unique benefit" to users. ER68:¶33. Again, how could "very strong momentum" and a "unique benefit" be associated with a dangerous product that had (a) prompted a scathing presentation to the American Rhinologic Society, and (b) already led to (undisclosed) product-liability litigation? These were no idle "puffing"

statements; rather, they were the sort of reassurances that mattered to investors. As such, they were both material and actionable.[13]

Finally, the Complaint clearly sets forth which defendant is responsible for which misstatement. Matrixx, of course, is responsible for ***all*** of the Class Period statements made on its behalf – whether set forth in a press release, or on a conference call. Thus, Matrixx itself made the false statements alleged at ER68:¶32 (press release), ER68:¶¶33-34 (conference call), ER68:¶35 (Form 10-Q filed with SEC), ER68:¶37 (press release), and ER68:¶38 (press release). But Matrixx is not the only defendant who "spoke" in this case.

Matrixx's Chief Executive Office and President Carl Johnson is actually ***quoted*** making several of the misleading public statements. *See* ER68:¶32 (press release); ER68:¶¶33-34 (conference call). Moreover, both Johnson and Matrixx's Chief Financial Officer William Hemelt signed the misleading Form 10-Q filed with the

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[13] "The materiality of management's views concerning" a company's progress and earnings prospects "is beyond doubt." *Elkind v. Liggett & Myers, Inc.*, 635 F.2d 156, 164 n.12 (2d Cir. 1980); *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1093 (1991) ("conclusory terms in a commercial context are reasonably understood to rest on a factual basis that justifies them as accurate, the absence of which renders them misleading"); *id*. at 1090 (even insiders' statements of belief or opinion can take on increased importance to shareholders, who know that insiders "usually have knowledge and expertness far exceeding the normal investor's resources").

SEC (ER68:¶35) – so there is no disputing that both men "made" the statements therein. *Howard v. Everex Sys.*, 228 F.3d 1057, 1061 (9th Cir. 2000).

Finally, each of the three men is also responsible for misstatements in Matrixx's press releases and the SEC filing. This Court has long recognized that 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). This makes sense, especially here: surely Hemelt, as Matrixx's top financial officer, would be responsible for a press release discussing the Company's financial prospects. *See* ER68:¶¶32, 37. By the same token, one would expect Matrixx Director of Research and Development Timothy Clarot to have contributed to the release denying alleged links between Zicam and anosmia as "completely unfounded and misleading." ER68:¶38. And it is reasonable to presume Matrixx President and CEO Johnson's involvement in each of the Company's major press releases, whether they concerned guidance going forward (ER68:¶37) or the Company's attempts at damage control (ER68:¶38) following news that the FDA was investigating a potential link between Zicam and anosmia, and that Zicam product-liability lawsuits had been filed. ER68:¶¶6-7.

Defendants insist that that PSLRA, despite not mentioning the group-published inference, nonetheless abolished it. Defs.' Brf. at 26 n.10. But the inference is

"grounded in reasonableness," *In re GlenFed, Inc. Sec. Litig.*, 60 F.3d 591, 593 (9th Cir. 1995) – and the PSLRA did not change the fact that plaintiffs still get the benefit of reasonable inferences in their favor. *Am. West*, 320 F.3d at 931. This includes group-published information. *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 439 (S.D.N.Y. 2005) ("the majority of courts in this and other jurisdictions have found that the doctrine is alive and well"); *In re Secure Computing Corp. Sec. Litig.*, 120 F. Supp. 2d 810, 821 (N.D. Cal. 2000) ("the majority of the district courts in the Ninth Circuit that have addressed the issue have concluded that the group published information presumption survives the PSLRA"). Defendants point out that two circuit courts have concluded that the inference is no longer viable (Defs.' Brf. at 26 n.10), but both courts made the same mistake by assuming the inference is used to allege a defendant's ***scienter***, versus his involvement in a group-published document.[14] *See, e.g.*, *BISYS*, 397 F. Supp. 2d at 440 (rejecting Fifth Circuit's holding in *INSpire*, because "the group pleading doctrine has no effect on the PSLRA's ***scienter*** requirement") (court's emphasis). The inference survives.

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[14] *See Southland Sec. Corp. v. INSpire Ins. Solutions Inc.*, 365 F.3d 353, 365 (5th Cir. 2004) ("'group pleading' doctrine conflicts with the scienter requirement of the PSLRA"); *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 602-03 (7th Cir. 2006) (assuming that group-published allegations were an attempt to comply with PSLRA's scienter requirement).

B. The Complaint's Allegations Raise a Strong Inference of Scienter

1. Defendants' Purported Lack of "Motive" Is Nothing but an Irrelevant Distraction from Facts that, Considered as a Whole, Raise a Strong Inference of Scienter

The district court – and now defendants – thought it important that the Complaint did not ascribe any "motivation" to defendants. ER88:13; Defs.' Brf. at 52-55. But, as plaintiffs' Opening Brief explained, it is beyond cavil that evidence of a defendant's "motive" is ***not*** required to satisfactorily plead a securities-fraud claim; deliberate recklessness or actual intent suffice. *See* Pltfs.' Brf. at 38-40; *see also Hanon*, 976 F.2d at 507; *Am. West*, 320 F.3d at 944 (scienter "can be established even if the officers who made the misleading statements did not sell stock during the class period"); *Ganino*, 228 F.3d at 170 ("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").

In response, defendants ignore both *Hanon* and *Ganino*.[15] Instead, they dredge up an unpublished district court slip opinion from 13 years ago that appears to demand a showing of "motive," and mention a few cases in which defendants' motive ***was***

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[15] Defendants do cite *Ganino* elsewhere in their brief, but not for its "motivation" holding. Defs.' Brf at 15 n.7 (judicial notice).

alleged. Defs.' Brf. at 52-53. That mention is a *non sequitur*, however, in light of the fact that motivation – while it may bolster scienter allegations – simply is not required.

Defendants also assert that this Court, in its post-PSLRA decisions, has not found a strong inference of scienter without there being at least "***some allegation of insider stock sales***." Defs.' Brf. at 53 (defendants' emphasis). But that case-specific happenstance does not matter here. This Court in *Am. West* said it plainly: "the lack of stock sales by a defendant is not dispositive as to scienter." 320 F.3d at 944. Defendants try to distinguish *Am. West* by pointing out the peculiar facts that supported a strong inference of scienter there, but just because defendants here did not receive direct warning letters from the FDA, or conduct meetings with FDA officials, does not mean that they were unaware of information directly contradicting their public statements.

To the contrary, defendants knew well before, and then during, the Class Period, that Zicam users were accusing the product of having caused their lost sense of smell. ER68:¶¶24-29. Matrixx's Vice President of Research and Development 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. Clarot admitted to Dr. Linschoten that

Matrixx had received complaints from ***other*** Zicam users as early as 1999, asserting that Zicam had caused their anosmia. *Id*. In September 2003 Matrixx learned of an upcoming presentation to the American Rhinologic Society that focused on Zicam-induced anosmia in at least ten individuals – and responded by demanding that the researchers omit any mention of "Zicam." ER68:¶28. Nine plaintiffs sued Matrixx in four product-liability suits during the Class Period. ER68:¶49. The FDA began investigating complaints of Zicam-induced anosmia sometime before January 30, 2004 – sobering news which defendants countered with a misleading press release.[16] ER68:¶¶40-41.

Considered in their totality, *Am. West.*, 320 F.3d at 945, the facts illustrate defendants' knowledge of specific information that contradicted their public representations concerning Zicam. No more is required – and certainly not more-definitive ***proof***, as defendants would have. *Green Tree*, 270 F.3d at 665 ("classic fact pattern[] giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to ***information suggesting*** that their

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[16] Defendants seek solace in the fact that the FDA never ordered Matrixx to withdraw Zicam from the market. Defs.' Brf. at 37. That does not mean much, however. For example, the popular "Vioxx" drug, despite causing an estimated 39,000 to 60,000 heart-attack deaths before Merck voluntarily pulled it off the market, "was never banned by the FDA." *See* Delthia Ricks, *Drug decisions cause outbreak of shock; recommendations by FDA panels that COX-2 drugs remain in use are criticized by doctors, activists*, Newsday, Feb. 20, 2005, at A24.

public statements were materially inaccurate") (emphasis added); *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (when defendants "***knew facts suggesting*** the statements were inaccurate or misleadingly incomplete is classic evidence of scienter") (emphasis added).

2. Defendants Unsuccessfully Attack Other Allegations that Help to Bolster the Strong Inference of Scienter

In addition to the above facts showing that Zicam-anosmia information was communicated to defendants before and during the time they were making contradictory public statements, the Complaint was able to allege even more circumstances that supported a strong inference of defendants' scienter. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 n.30 (1983) (noting that circumstantial evidence can constitute proof of scienter in fraud cases). The circumstances included Zicam's undisputed importance to Matrixx's bottom line, and the close temporal proximity between defendants' misstatements and contradictory post-Class Period events.

Defendants' attempts to denigrate these additional allegations are unsuccessful.

They say the "core product" inference works only when critical facts both "exist" and "have been communicated to a company." Defs.' Brf. at 56. Plaintiffs agree with that statement – for Matrixx was specifically warned, in 1999, 2002, and again in 2003-2004, of the existence of a ***critical*** fact: Zicam users were complaining that the product had caused them to lose their sense of smell. Zicam users complained

to Matrixx, as did medical doctors and researchers. ER68:¶¶24-26, 28. Lawsuits were being filed! ER68:¶49. Defendants even went so far as to contact one of the complaining doctors (and admit to her that Matrixx had received similar complaints), and warned another doctor to excise the Zicam name from a blockbuster medical society presentation. ER68:¶¶26-27, 29. Defendants quibble whether the complaints were "credible" (Defs.' Brf. at 57), but that is a determination better left for a fact finder. *Levan v. Capital Cities/ABC, Inc.*, 190 F.3d 1230, 1240 n.29 (11th Cir. 1999); *United States v. Holleman*, 575 F.2d 139, 145 (7th Cir. 1978).

Defendants argue that the temporal proximity allegations are nothing more than "fraud by hindsight" because plaintiffs have pointed to post-Class Period events. Their argument is overbroad, however, for by definition a temporal-proximity argument will ***always*** point to some later event. Impermissible "fraud by hindsight," on the other hand, occurs when a plaintiff "simply contrast[s] a defendant's past optimism with less favorable actual results, and then 'contend[s] that the difference must be attributable to fraud.'" *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1223 (1st Cir. 1996) (citation omitted).

But that is not what plaintiffs here did; rather, plaintiffs accurately reported defendants' insistence on February 2, 2004, that allegations about Zicam-linked anosmia were "***completely unfounded***," and that "***no clinical trial***" had reported any lost or diminished sense of smell – and compared that insistence with defendants'

admission, just two weeks later, that there was actually "insufficient scientific evidence" available to say ***whether or not*** Zicam did indeed affect sense of smell. ER68:¶¶38, 41, 45-47 (emphasis added). Defendants conceded that they were ***then*** going to begin animal and human testing to determine whether the alleged link existed. ER68:¶47.[17] The contradiction is obvious.

Plaintiffs also were able to point to the peer-reviewed publication in the *American Journal of Rhinology*, soon after the Class Period, of the Jafek-Linschoten-Murrow study that defendants had known back in September 2003 was to be presented to the American Rhinologic Society. Defendants really have no response, other than to parrot the district court's incorrect conclusion that the 2004 publication was "irrelevant" to defendants' state of mind during the Class Period. Defs.' Brf. at 58; *id*. at 58 n.15 (publication has "no bearing" on defendants' knowledge during Class Period). But the record reflects that the peer-reviewed, published information was the ***same*** information defendants knew about during the Class Period. ER68:¶64; *see also* Transcript at 35:18-36:12 (counsel informs court that same research "was ultimately subjected to peer review, passed peer review and was published" in the

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[17] Plaintiffs agree with defendants that temporal proximity alone may not suffice, but point out that the Complaint is replete with other allegations bolstering a strong inference of scienter.

American Journal of Rhinology). The district court erred in not accepting the allegation as true.

The court compounded its error by holding that the information's relevance to defendants' state of mind in 2003 turned on its "reliab[ility]" and whether it was already peer-reviewed. ER88:12. The district court overstepped its authority by deciding for itself, on a motion to dismiss, the weight to be accorded the study. *Jones v. Johnson*, 781 F.2d 769, 772 n.1 (9th Cir. 1986) ("any weighing of the evidence is inappropriate on a 12(b)(6) motion"); *Neitzke*, 490 U.S. at 327; *Goldman*, 754 F.2d at 1067. Moreover, the facts show that the September presentation, peer-reviewed or not at that time, ***was*** taken seriously by defendants – they reacted to it by twice writing Dr. Jafek (ER68:¶29), and by convening a panel of doctors and scientists ***in direct response to it***! *See* ER68:¶45 (defendants admit two-day Zicam-anosmia meeting "was held in response to" the September 2003 poster presentation). Defendants, and the district court, are wrong to dismiss either version of the Jafek-Linschoten-Murrow materials as irrelevant to defendants' knowledge.[18]

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[18] Should this Court wish to view either version of the Jafek-Linschoten-Murrow materials referenced in the Complaint, they are available on the Internet. *See* http://www.coldcure.com/anosmia/jafek.ppt (September 2003 presentation to the American Rhinologic Society) and http://coldcure.com/anosmia/jafek-zicam-anosmia.pdf (peer-reviewed publication in the *American Journal of Rhinology* in the *Journal*'s May-June 2004 issue).

Finally, while the large number of post-Class Period personal-injury lawsuits against Matrixx are not dispositive on the scienter issue, nor are they completely irrelevant. Even the district court acknowledged that the hundreds of lawsuits "may very well be relevant to Defendants' knowledge of user complaints." ER88:6. The plaintiffs in each one alleged that Zicam had damaged their sense of smell. ER68:¶49. This is the same charge that defendants knew had been leveled at Matrixx since at least 1999; defendant Clarot admitted as much to Dr. Linschoten. ER68:¶26. It was the same charge alleged by nine personal-injury plaintiffs during the Class Period. ER68:¶49. Thus, it was not "sheer speculation" that Matrixx should have anticipated additional suits given the Class Period complaints. Defs.' Brf. at 59. *See Novak v. Kasaks*, 216 F.3d 300, 313 (2d Cir. 2000) (post-class period events help support inference of class-period problems).

At bottom, when considered in their entirety the alleged facts raise a strong inference of defendants' scienter.

II. CONCLUSION

The dismissal with prejudice should be reversed.

DATED: November 13, 2006

Respectfully submitted,

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
WILLIAM S. LERACH
DARREN J. ROBBINS
JOSEPH D. DALEY
SCOTT H. SAHAM

JOSEPH D. DALEY

655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
SAMUEL H. RUDMAN
DAVID A. ROSENFELD
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

BONNETT, FAIRBOURN, FRIEDMAN
& BALINT, P.C.
ANDREW S. FRIEDMAN
FRANCIS J. BALINT, JR.
2901 N. Central Avenue, Suite 1000
Phoenix, AZ 85012-3311
Telephone: 602/274-1100
602/274-1199 (fax)

CAVANAGH & O'HARA
PATRICK O'HARA
407 East Adams
Springfield, IL 62701
Telephone: 217/544-1771
217/544-9894 (fax)

Attorneys for Plaintiffs-Appellants

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CERTIFICATE OF COMPLIANCE

The undersigned counsel certified that Plaintiffs-Appellants' Reply Brief uses a proportionally spaced Times New Roman typeface, 14-point, and that the text of the brief comprises 6,985 words according to the word count provided by Microsoft Word 2002 word processing software.

JOSEPH D. DALEY
COUNSEL FOR PLAINTIFFS-APPELLANTS

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 November 13, 2006, declarant served **PLAINTIFFS-APPELLANTS' REPLY BRIEF** by depositing two 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' REPLY 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 13th day of November, 2006, at San Diego, California.

JANA P. KUSY