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16 UNITED STATES DISTRICT COURT

17 DISTRICT OF ARIZONA

18 JAMES V. SIRACUSANO, On Behalf of
Himself and All Others Similarly Situated,

19 Plaintiff,

20 vs.

21 MATRIXX INITIATIVES, INC., et al.,

22 Defendants.
23

Civ. No. 04-0886-PHX-MHM
(Consolidated)

CLASS ACTION

NOTICE OF APPEAL AND NINTH
CIRCUIT RULE 3-2 REPRESENTATION
STATEMENT

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1 Notice is hereby given that plaintiffs in the above-captioned case (lead plaintiff
2 NECA-IBEW Pension Fund and named plaintiff James Siracusano), on behalf of themselves
3 and all others similarly situated, hereby appeal to the United States Court of Appeals for the
4 Ninth Circuit from the final judgment that was entered on March 8, 2006, and all prior orders
5 (including, but not limited to, the December 15, 2005, order dismissing the case with
6 prejudice that was entered on March 8, 2006).

7 DATED: April 3, 2006

Respectfully submitted,

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RULE 3-2 REPRESENTATION STATEMENT

Plaintiffs in this action, NECA-IBEW Pension Fund and James Siracusano, on behalf of themselves and all others similarly situated, are represented by the following counsel:

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CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2006, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

s/ SCOTT H. SAHAM
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Mailing Information for a Case 2:04-cv-00886-MHM

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Manual Notice List

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USCA DOCKET # (IF KNOWN)

**UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT
CIVIL APPEALS DOCKETING STATEMENT**

PLEASE ATTACH ADDITIONAL PAGES IF NECESSARY.

TITLE IN FULL: Siracusano, et al. v. Matrixx Initiatives, Inc., et al.	DISTRICT: Arizona JUDGE: Hon. Mary Murguia	
	DISTRICT COURT NUMBER: 04-0886-PHX-DKD	
	DATE NOTICE OF APPEAL FILED: April 3, 2006	IS THIS A CROSS-APPEAL? <input type="checkbox"/> YES
	IF THIS MATTER HAS BEEN BEFORE THIS COURT PREVIOUSLY, PLEASE PROVIDE THE DOCKET NUMBER AND CITATION (IF ANY):	

BRIEF DESCRIPTION OF NATURE OF ACTION AND RESULT BELOW:
 Class action alleging securities fraud filed against Matrixx and several of its top officers. The district court dismissed with prejudice, entering judgment on March 8, 2006.

- PRINCIPAL ISSUES PROPOSED TO BE RAISED ON APPEAL:**
- Whether the district court erred in dismissing with prejudice plaintiffs' Consolidated Amended Complaint.
 - Whether the district court erred in (partially) granting defendants' motion to strike portions of the Consolidated Amended Complaint.

PLEASE IDENTIFY ANY OTHER LEGAL PROCEEDING THAT MAY HAVE A BEARING ON THIS CASE (INCLUDE PENDING DISTRICT COURT POSTJUDGMENT MOTIONS):

- DOES THIS APPEAL INVOLVE ANY OF THE FOLLOWING:**
- Possibility of settlement
 - Likelihood that intervening precedent will control outcome of appeal
 - Likelihood of a motion to expedite or to stay the appeal, or other procedural matters (Specify) _____
 - Any other information relevant to the inclusion of this case in the Mediation Program _____

Possibility parties would stipulate to binding award by Appellate Commissioner in lieu of submission to judges


LOWER COURT INFORMATION

JURISDICTION		DISTRICT COURT DISPOSITION	
FEDERAL	APPELLATE	TYPE OF JUDGMENT/ORDER APPEALED	RELIEF
<input checked="" type="checkbox"/> FEDERAL QUESTION <input type="checkbox"/> DIVERSITY <input checked="" type="checkbox"/> OTHER (SPECIFY): and 15 U.S.C. §78aa	<input checked="" type="checkbox"/> FINAL DECISION OF DISTRICT COURT <input type="checkbox"/> INTERLOCUTORY DECISION APPEALABLE AS OF RIGHT <input type="checkbox"/> INTERLOCUTORY ORDER CERTIFIED BY DISTRICT JUDGE (SPECIFY): <input type="checkbox"/> OTHER (SPECIFY):	<input type="checkbox"/> DEFAULT JUDGMENT <input type="checkbox"/> DISMISSAL/JURISDICTION <input checked="" type="checkbox"/> DISMISSAL/MERITS <input type="checkbox"/> SUMMARY JUDGMENT <input checked="" type="checkbox"/> JUDGMENT/COURT DECISION <input type="checkbox"/> JUDGMENT/JURY VERDICT <input type="checkbox"/> DECLARATORY JUDGMENT <input type="checkbox"/> JUDGMENT AS A MATTER OF LAW <input type="checkbox"/> OTHER (SPECIFY):	<input checked="" type="checkbox"/> DAMAGES: To be determined SOUGHT \$ _____ AWARDED \$ _____ <input type="checkbox"/> INJUNCTIONS: <input type="checkbox"/> PRELIMINARY <input type="checkbox"/> PERMANENT <input type="checkbox"/> GRANTED <input type="checkbox"/> DENIED <input type="checkbox"/> ATTORNEY FEES: SOUGHT \$ _____ AWARDED \$ _____ <input type="checkbox"/> PENDING <input type="checkbox"/> COSTS: \$ _____

CERTIFICATION OF COUNSEL

I CERTIFY THAT:

- COPIES OF ORDER/JUDGMENT APPEALED FROM ARE ATTACHED.
- A CURRENT SERVICE LIST OR REPRESENTATION STATEMENT WITH TELEPHONE AND FAX NUMBERS IS ATTACHED (SEE 9TH CIR. RULE 3-2).
- A COPY OF THIS CIVIL APPEALS DOCKETING STATEMENT WAS SERVED IN COMPLIANCE WITH FRAP 25.
- I UNDERSTAND THAT FAILURE TO COMPLY WITH THESE FILING REQUIREMENTS MAY RESULT IN SANCTIONS, INCLUDING DISMISSAL OF THIS APPEAL.


 Signature

April 3, 2006
 Date

COUNSEL WHO COMPLETED THIS FORM

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***THIS DOCUMENT SHOULD BE FILED IN THE DISTRICT COURT WITH THE NOTICE OF APPEAL*
 *IF FILED LATE, IT SHOULD BE FILED DIRECTLY WITH THE U.S. COURT OF APPEALS***

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

James V. Siracusano,)
)
 Plaintiff(s),) CIV-04-886-PHX-MHM
) CIV-04-1012-PHX-MHM
 v.) (Consolidated)
)
 Matrixx Initiatives, Inc.,) JUDGMENT
 et al.,)
)
 Defendant(s).)
 _____)

_____ **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

XXX **Decision by Court.** This action came for consideration before the Court. The issues have been considered and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that this Court having granted Defendants' Motion to Dismiss, Plaintiffs take nothing. This Complaint and action are hereby dismissed without prejudice.

DATED at Phoenix, Arizona, this 8th day of March, 2006.

RICHARD H. WEARE
DCE/Clerk of Court

By: s/ M. Pruneau
Deputy Clerk

CIV-21 (7/94)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

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10 James V. Siracusano, on Behalf of Himself
and All Other Similarly Situated,

No. CIV-04-0886-PHX-MHM
No. CIV-04-1012-PHX-MHM
(consolidated)

11 Plaintiff,

12 vs.

ORDER

13 Matrixx Initiatives, Inc.; Carl J. Johnson;
William J. Hemelt; and Timothy L. Clarot,

14 Defendants.
15

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

21 **I. Factual and Procedural Background**

22 Defendant-Matrixx Initiatives Inc., ("Matrixx") develops and markets over-the-
23 counter pharmaceuticals. Zicam, Matrixx's wholly-owned subsidiary, produces Zicam Cold
24 Remedy. Between October 22, 2003 and February 6, 2004 ("Class Period"), Plaintiffs
25 purchased thousands of Matrixx shares and instituted this class action on behalf of all
26 purchasers during the Class Period. Am. Compl. ¶1. Plaintiffs allege that Matrixx and its
27 officers violated the Securities and Exchange Act by issuing materially false and misleading
28

1 statements concerning Zicam. Specifically, Plaintiffs assert Matrixx knew that Zicam may
2 cause users to suffer a total and permanent loss of smell, known as anosmia. Further,
3 Plaintiffs assert that while Matrixx warned investors that there was a potential for such
4 lawsuits, Matrixx materially misled investors by not alerting them that such lawsuits had
5 already been filed.

6 Plaintiffs allege in 1999 Dr. Alan Hirsh M.D., Neurological Director of the Smell &
7 Taste Treatment and Research Foundation, Ltd., recognized a link between Zicam use and
8 anosmia and reported the possible link to Matrixx's customer service line and to a Mr.
9 Landau. Id. at ¶25. In September 2002, Timothy L. Clarot, Matrixx's Vice President and
10 Miriam R. Linchosten, Ph.D., of the University of Colorado, corresponded regarding a Zicam
11 user complaining of anosmia and regarding studies linking zinc sulfate to anosmia. Id. at
12 ¶¶26, 27. In September 2003, a collaborative research effort by medical researchers at the
13 University of Colorado School of Medicine, Department of Otolaryngology, et al.
14 ("University of Colorado Study") identified 11 Zicam users who had suffered from anosmia.
15 Am. Compl. ¶¶3, 24, 28. As of April 2004, Doctro Jafek had evaluated over 100 cases of
16 anosmis and Dr. Linchosten estimated she had treated 65 users of Zicam who suffered from
17 anosmia. Id.

18 Defendants did not disclose the University of Colorado study and instead informed
19 Dr. Bruce Zafek, of the University of Colorado, that "as a legal matter [the University of
20 Colorado] did not have [Matrixx's] permission to use their company name or product
21 trademarks" in association with the University of Colorado study. Id. at ¶¶4,29. Plaintiffs
22 contend despite knowledge of the risk of anosmia, Defendants continued to make positive
23 statements regarding Matrixx's growth and revenue and Zicam's safety. Specifically, on
24 October 22, 2003, Matrixx issued a press release indicating net sales increased by 164% by
25 the third quarter of 2002 and stating "[t]he Zicam brand is poised for growth in the upcoming
26 cough and cold season" and the Zicam brand is relied on "as an efficacious product." Id. at
27 32. Again, on October 23, 2003 in a conference call with financial analyst, Defendant
28

1 Johnson stated “we are extremely encouraged at this point . . . what lies beyond these results
2 is a unique product in the Zicam product line. A product that offers a unique benefit, the
3 ability for consumers to actually reduce the duration and severity of the common cold, not
4 just mask the symptoms.” Id. at 33.

5 In a November 12, 2003 quarterly report, Defendants reiterated positive projections
6 with a disclaimer “We may incur significant costs resulting from product liability claims.”
7 Id. At 35. On February 2, 2004, Plaintiff Matrixx issued a press release stating:

8 Matrixx believes statements alleging that intranasal Zicam
9 products cause anosmia (loss of smell) are completely
10 unfounded and misleading. In no clinical trial of intranasal zinc
11 gluconate gel products has there been a single report of lost or
12 diminished olfactory function. Rather, the safety and efficacy
of zinc gluconate for the treatment of symptoms related to the
common cold have been well established in two double-blind,
placebo-controlled, randomized clinical trials. In fact, in neither
study were there any reports of anosmia related to the use of this
compound

13 Id. at 38

14 On January 30, 2004 an article published in the *Dow Jones Wire* indicated three
15 product liability suits related to the use of Zicam had been filed. Id. at ¶¶6,40. On February
16 2, 2004, Matrixx representatives issued a press release stating that “statements alleging
17 intranasal Zicam products cause anosmia are completely unfounded and misleading.” Id. at
18 ¶6. Additionally Matrixx stated “[i]n no clinical trial of intranasal zinc gluconate gel
19 products [active ingredient in Zicam] has there been a single report of loss or diminished
20 olfactory function.” Id.

21 On February 6, 2004, *Good Morning America* reported the University of Colorado
22 study demonstrated Zicam may cause users to suffer from anosmia, four product liability
23 lawsuits related to Zicam users suffering from anosmia were pending, and similar lawsuits
24 were expected. Id. at ¶¶8,42. The lawsuits were filed from October 2003 to January 2004.
25 Id. at 49. Also on February 6, 2004, Matrixx issued a press release entitled “Reaffirm[ing]
26 safety of intranasal Zicam Cold Remedy” and reiterating that there had been no clinical trial
27 of intranasal zinc gluconate gel causing anosmia. Id. at ¶9. On February 5, 2004, after the

28

1 *Good Morning America* broadcast, the price of Matrixx common stock fell 23.8%. *Id.* at
2 ¶¶8,43. After meeting with physicians, on February 19, 2004, Defendants filed a Form 8-K
3 with the Security Exchange Commission ("SEC") stating "[i]n the opinion of the panel, there
4 is insufficient scientific evidence at this time to determine if zinc glutonate, when used as
5 recommended, affects a person's ability to smell." *Id.* at ¶46.

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

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

16 **II. Motion to Strike**

17 **A. Legal Standard**

18 Fed. R. Civ. P. 12(f) provides that a party may bring a motion to strike to request the
19 Court to remove insufficient defenses as well as "redundant, immaterial, impertinent, or
20 scandalous matter" that might otherwise prejudice a party. *E.g., Fantasy, Inc. v. Fogerty*, 984
21 F.2d 1524, 1527 (9th Cir.1993), *rev'd on other grounds*, 510 U.S. 517 (1994). Motions to
22 strike are disfavored because they are "often used as delaying tactics, and because of the
23 limited importance of pleadings in federal practice." *Colaprico v. Sun Microsystems, Inc.*,
24 758 F. Supp. 1335, 1339 (N.D. Cal.1991). However, the Court may grant a motion to strike
25 if the party can establish that the statements at issue would prejudice the moving party, or
26 that striking the statements would streamline the case. *Fogerty*, 984 F.2d at 1528.

27 **B. Discussion**

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

6 Courts in this circuit have stricken as irrelevant claims in a complaint alleging fraud
7 and insider trading outside of the class period. See In re Clearly Canadian Sec. Litig., 875
8 F. Supp. 1410, 1420 (N.D. Cal. 1995). Furthermore, Congress enacted the Reform Act to
9 put an end to the practice of pleading "fraud by hindsight." See e.g., Medhekar v. United
10 States Dist. Ct., 99 F.3d 325, 328 (9th Cir.1996) (holding that Congress intended for
11 complaints under the Reform Act to stand or fall based on the actual knowledge of the
12 plaintiffs rather than information produced after the action has been filed).

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

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

28

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

8
9 **III. Standard of Review**

10 Under FED. R. CIV. PRO. Rule 12(b)(6), the court will not dismiss a complaint unless
11 it appears beyond a doubt that the plaintiff can prove no set of facts to support the claim that
12 would entitle the plaintiff to relief. Morley v. Walker, 175 F.3d 756, 759 (9th Cir. 1999). In
13 determining whether a complaint states a claim, all allegations of material fact are taken as
14 true and construed in the light most favorable to the nonmoving party, her Plaintiffs. Wylar
15 Summit P'ship v. Turner Broad. Sys., Inc., 135 F.3d 658, 661 (9th Cir. 1998). However, "the
16 court [is not] required to accept as true allegations that are merely conclusory, unwarranted
17 deductions of fact, or unreasonable inferences." Sprewell v. Golden State Warriors, 266 F.3d
18 979, 988 (9th Cir. 2001). Additionally, while the Court's primary focus is on allegations
19 contained in the pleadings, the Court may also consider documents attached to the complaint
20 or incorporated by reference. In re Northpoint Communications Group, Inc., 221 F. Supp.
21 2d 1090 (N.D. Cal. 2002). Furthermore, judicial notice of documents filed with the Security
22 Exchange Commission is proper in actions alleging securities fraud. See e.g., Allison v.
23 Brooktree Corp., 999 F. Supp. 1342, 1352 n.3 (S.D. Cal. 1998).

24 Rule 9(b) also imposes particularized pleading requirements on a plaintiff alleging
25 fraud or any claim premised on fraud such that all averments of fraud or mistake must be
26 stated with particularity. FED. R. CIV. PRO. 9(b) (2005). Additionally, an action brought
27 under the Reform Act is subject to heightened pleading standards that are more rigorous than

1 the Rule 9(b) standards. The Reform Act requires the plaintiff to "specify each statement
2 alleged to have been misleading, the reason or reasons why the statement is misleading, and,
3 if an allegation regarding the statement or omission is made on information or belief, the
4 complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C.
5 § 78u-4(b)(1). The complaint must also state with particularity facts giving rise to a
6 strong inference that the defendant acted with the required state of mind with respect to each
7 act or omission alleged to violate securities law. 15 U.S.C. § 78u-4(b)(2). The required state
8 of mind is deliberate recklessness. In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 977
9 (9th Cir.1999). However, if the alleged material false statement or omission is a
10 "forward-looking statement," the required level of scienter is actual knowledge. 15 U.S.C.
11 § 78u-5(c)(1)(B). A motion to dismiss the complaint must be granted if the complaint fails
12 to satisfy these requirements. 15 U.S.C. § 78u-4(b)(3)(A).

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

22 IV. Discussion

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

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4 **A. Misstatement or Omission of Material Fact**

5 Under the Reform Act, to adequately allege securities fraud a complaint must specify
6 each statement alleged to have been misleading, the reason or reasons why the statement was
7 misleading and, if an allegation is made on information and belief, all facts upon which that
8 belief is formed. 15 U.S.C. 78u-4(b)(1). An omission is actionable under Section 10(b) if the
9 omitted fact is material – that is, its disclosure to necessary to prevent another statement from
10 being materially misleading. Id. Plaintiffs allege two general categories of statements and
11 omissions prior to the end of the class period are actionable: statements regarding the safety
12 of Zicam without disclosing a link between Zicam and anosmia and statements related to
13 Zicam's commercial and financial potential. In essence, Plaintiffs contention is Defendants'
14 knowledge of the University of Colorado study, user complaints, and four product-liability
15 class actions gave rise to a duty to disclose and correct statements relating to Zicam's safety,
16 profitability, and especially statements that there had been no clinical trial showing intranasal
17 zinc gluconate gel causes anosmia.

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

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

4 The plaintiffs in Carter-Wallace complained about the failure to disclose the adverse
5 medical reports which were received before July 1994, and alleged that such failure
6 indirectly inflated the market price of the Carter-Wallace stock. The Second Circuit held that
7 there was no sufficient allegation of a knowing withholding of material information. There
8 was no indication, said the court, that Carter-Wallace knew, or should have known, before
9 August 1, 1994, of the connection between Felbatol and aplastic anemia. Carter-Wallace,
10 Inc., 220 F.3d at 42. The court stated: "Here, the early medical reports may have indicated
11 a potential problem, but until a connection between Felbatol and any illness could be made,
12 we would not expect Carter-Wallace to abandon its product on what, at the time, would have
13 been speculation." Id. The court took the view that Carter-Wallace was not dishonest or
14 reckless in viewing the earlier reports as merely "random" instances of disease (i.e., not
15 necessarily caused by Felbatol). The court noted: "Felbatol had, after all, survived the
16 extensive testing process required by the FDA. Id. The court also stated that
17 "Carter-Wallace's financial statements would not ... become materially misleading until
18 Carter-Wallace had information that Felbatol had caused a *statistically significant* number
19 of aplastic anemia deaths and therefore had reason to believe that the commercial viability
20 of Felbatol was threatened." Id. at 40 (emphasis added)

21 While, subsequent courts have noted Carter-Wallace does not provide a "bright-line
22 pleading standard" for securities fraud claims where those claims are "based upon alleged
23 failure to disclose adverse medical reports," other circuits have followed the reasoning in
24 Carter-Wallace, concluding that Defendants must have statistically significant information
25 before statements related to a products drug safety become material. Oran v. Stafford, 226
26 F.3d 275, 284 (3d.Cir. 2000) (holding "[b]ecause the link between the . . . drugs and heart-
27 valve disorders was never definitively established during the relevant period even after the

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1 withdrawal data is taken into account [defendant's] failure to disclose this data cannot render
2 its statements about inconclusiveness of the relationship materially misleading"); see also In
3 re Alliance Pharm. Sec. Litig., 279 F. Supp. 2d 171, 189 (finding there was a genuine issue
4 of material fact regarding whether failure to include information in prospectus that test group
5 would change in composition was a material omission, after noting "not every adverse effect
6 in a clinical trial is automatically material, and that causation, as well as statistical
7 significance, is key").

8 However, where a company is presented with statistically significant adverse medical
9 reports, adverse clinical data, and a "consensus emerge[s] that the data" is "putting the brand
10 at risk," then courts have found a material omission. In re Bayer AG Sec. Litig., No 03
11 CIV.1546 WHP, 2004 WL 2190357, *4 (S.D.N.Y. Sept. 20, 2004) (unpublished opinion).
12 In Bayer AG, Defendants received repeated and numerous adverse event reports indicating
13 its drug Baycol, a cholesterol-lowering drug, caused rhabdomyolysis, an acute sometimes
14 fatal serious muscle disease. However, Defendants repeatedly touted the efficacy, safety, and
15 profitability of Baycol. In fact, the District Court noted by 1999 "adverse event reports were
16 inundating Bayer" with 60 cases of rhabdomyolysis in the preceding 2 months in the United
17 States. Id. Still, the District Court concluded Defendants only had a duty to correct previous
18 statements as to Baycol's safety and future profitability as of August 2000, when Bayer's
19 consultants met and "a consensus emerged that the data concerning Baycol's dangers 'was
20 putting the brand at risk.'" The District Court reasoned it was only after the consensus
21 emerged was the data on Baycol "sufficiently serious and frequent to affect future earnings."
22 Id. at *10; see also DeMarco v. DepoTech Corp., 32 Fed. Appx. 260 (9th Cir. 2002)
23 (complaint failed to satisfy Reform Act pleading requirements where it alleged merely that
24 drug manufacturing company's officers made positive statements about product's prospects
25 after receiving negative clinical trial reports and failed to particularly identify which reports
26 were contradicted by contemporaneous positive statements, nor any details as to how officers
27 were made aware of said reports).

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1 The above cases recognize that test results and user complaints are not always
2 material, requiring disclosures. "Medical researchers may well differ with respect to what
3 constitutes acceptable testing procedures, as well as how best to interpret data garnered under
4 various protocols." Pasnes v. Scios Nova inc., No C 95-1693, 1996 WL 539711, *5 (N.D.
5 Cal. Sept. 18, 1996). The Food and Drug Administration ("FDA") similarly recognizes that
6 experts can find test results difficult to interpret. In explaining to Congress why the FDA
7 insists that applicants provide all test data to the agency instead of only summaries, that
8 agency has stated:

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

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

19 Similarly, Matrixx conducted a double-blind study regarding Zicam and not a single
20 case of anosmia was reported. The Amended Complaint provides the following allegations
21 of links between Zicam and anosmia for which Defendants had knowledge: a phone
22 conversation between a Matrixx vice-president and University of Colorado researcher
23 discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University
24 of Colorado study citing 11 cases of anosmia in Zicam users. Similar to Carter-Wallace,
25 Plaintiffs present minimal evidence of Zicam complaints during the class period. Zicam is
26 a homeopathic remedy, and therefore is not subject to the same FDA approval as in Carter-
27 Wallace. Nonetheless, the Court finds the adverse medical reports of Felbatol and user
28 complaints here analogous. Simply, there is no data as to the reliability and accuracy of the
user complaints. Even if there were data as to the reliability, the Court finds 12 user
complaints is not statistically significant. While the Complaint cites to 165 other complaints,
it fails to allege those user complaints were within the class period or that Defendants had

1 any knowledge of the complaints. Moreover, Plaintiffs have failed to allege that during the
2 class period, Defendants were presented with any evidence that the University of Colorado
3 study was reliable, the methodology used, or that it was subject to peer review. Based on the
4 foregoing, the Court finds that as of the close of the class period, Plaintiff's have failed to
5 present evidence of a statistically significant correlation between the use of Zicam and
6 anosmia so as to make failure to publically disclose complaints and the University of
7 Colorado study a material omission.

8 **B. Scierter**

9 The complaint must also state with particularity facts giving rise to a strong inference
10 that the defendant acted with the required state of mind with respect to each act or omission
11 alleged to violate securities law. 15 U.S.C. § 78u-4(b)(2). The required state of mind is
12 deliberate recklessness. In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 977 (9th
13 Cir.1999). However, if the alleged material false statement or omission is a "forward-looking
14 statement," the required level of scierter is actual knowledge. 15 U.S.C. § 78u-5(c)(1)(B).

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

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

1 Here, the Complaint fails to allege any motive or state of mind with relation to the
2 alleged omissions. Plaintiffs argue that Defendants actions in informing Dr. Jafek, that the
3 University of Colorado did not have permission to use Zicam marks is evidence of scienter.
4 However, the argument is not well taken. It is just as reasonable to infer, Defendants were
5 appropriately protecting Zicam's good name and marketability. Furthermore, in the letter
6 from an Allied Waste researcher informing Dr. Jafek he did not have permission to use
7 Zicam marks, Mr. Clarot stated "we are very much interested in learning more about adverse
8 reports included in your presentation and, to the extent you have valid clinical data
9 supporting your conclusions, we would appreciate receiving that immediately." Longo Decl.
10 Ex. 1. There are no allegations Defendants disbelieved their statements as to the safety of
11 Zicam, Defendants profited, or attempted to profit from public statements.

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

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1 other than the conclusory allegation there was a duty to disclose the one product liability
2 lawsuit filed at the time of the third quarter 10-Q. Plaintiffs have failed to allege a loss was
3 reasonable foreseeable or any other overstatement giving rise to an inference of deliberate
4 recklessness.

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

16 Given the fact Plaintiffs have alleged 165 user complaints in the First Amended
17 Complaint, that the University of Colorado study was ultimately peer reviewed, and
18 Defendants' knowledge during the Class Period is unclear, the Court will dismiss the First
19 Amended Complaint without prejudice. However, Plaintiffs should take note that allegations
20 of post-Class period user complaints, post-Class Period links between Zicam and anosmia,
21 and post-Class Period publication of the University of Colorado study, lending it credibility,
22 are wholly insufficient to cure the deficiencies in the First Amended Complaint. Absent
23 allegations Defendants *knew* there was a definitive and statistically significant link between
24 Zicam and anosmia *during the Class Period* that was "sufficiently serious and frequent to
25 affect future earnings," any amendment would be futile.

26 **Accordingly**

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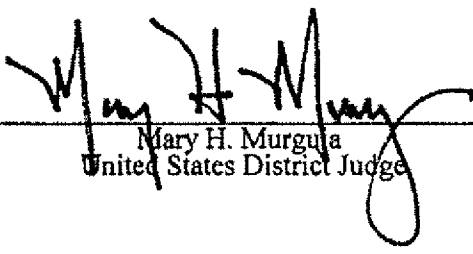
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IT IS HEREBY ORDERED Defendants' Motion to Strike is **GRANTED IN PART**
AND DENIED IN PART. (Dkt. #72)

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

DATED this 15th day of December, 2005.



Mary H. Murgula
United States District Judge