

The Nose Knows: What the Supreme Court's
Decision in *Matrixx v. Siracusano* Says About
Pleading Materiality and Scier in §10(b) Claims

by

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INTRODUCTION

In *Matrixx Initiatives, Inc. v. Siracusano*¹, the Supreme Court considered whether the respondents, a class of investors who purchased *Matrixx* securities on the national market between October 22, 2003, and February 6, 2004 (the “Class Period”), had adequately alleged a claim under § 10(b) of the Securities Exchange Act of 1934² and the Securities and Exchange Commission (SEC) Rule 10b-5³, based on the petitioner pharmaceutical company’s alleged

¹ 563 U.S. ____ (2011)

² 15 U.S.C. § 78(j)(b)

³ 17 C.F.R. § 240.10b-5(2010)

failure to disclose “adverse event reports”⁴ associated with the homeopathic cold remedy Zicam, despite the fact that these reports did not constitute a statistically significant number of adverse events.

The Court, in a unanimous decision, declined to adopt a bright-line rule that “reports of adverse events associated with a pharmaceutical company’s products cannot be material absent a significant number of such reports.”⁵ Instead, applying the “total mix” standard articulated in *Basic, Inc. v. Levinson*⁶, the Court concluded that “assessing the materiality of adverse event reports is a ‘fact-specific’ inquiry that requires consideration of the source, content, and context of the reports.”⁷ The Court concurred with the Ninth Circuit in holding that in the instant case, respondents had adequately pleaded materiality.⁸ Additionally, the Court held that the respondents had adequately plead the scienter required for a successful 10b-5 claim, assuming without deciding that the “deliberate recklessness” standard applied by the Ninth Circuit was sufficient to establish scienter.⁹ The Court stated that “[t]he inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that it simply thought the reports did not indicate anything meaningful about adverse reactions.”¹⁰

⁴ See 21 C.F.R. § 314.80(a) (2010). The FDA defines an “[a]dverse drug experience” as “[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related.” During the Class Period, Matrixx was not required to disclose adverse event reports to the FDA, as Zicam Cold Remedy was sold as an over-the-counter drug. In 2006, Congress enacted legislation that required manufacturers of nonprescription drugs to report “any report received of a serious adverse event associated with such drug.” 21 U.S.C. §§379aa(b), (c). The FDA has defined a “serious adverse event” as “[a]ny adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.” 21 C.F.R. § 314.80(a)(2010).

⁵ *Matrixx*, 563 U.S. _____, at 11 (2011).

⁶ 485 U.S. 224, 236 (1988)

⁷ *Matrixx*, 563 U.S. _____, at 15 (2011).

⁸ *Id.* at 16.

⁹ *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d. 1167, 1180 (2009).

¹⁰ *Matrixx*, 563 U.S. _____, at 21.

Part One of this paper will trace the factual and procedural background of this case as it progressed to being heard by the Court. Part Two will discuss the general legal principles of materiality and scienter in the context of securities fraud class actions, as well as analyze adverse event reporting and statistical significance. Part Three will discuss the opinion rendered by the Court in detail, and in particular the reasons why the Court declined to establish a bright-line rule in this area of securities litigation. Part Four will conclude by analyzing the impact of this decision on future securities fraud litigation, and discuss the potential problems for both drug manufacturers and investors that may arise from this decision.

I. FACTUAL AND PROCEDURAL BACKGROUND

The class of investors in *Matrixx* alleged the following facts in their complaint, which the lower courts assumed to be true in the context of deciding a motion to dismiss.¹¹ *Matrixx* Initiatives, Inc. (“*Matrixx*”) is a pharmaceutical company that sells over-the-counter cold remedy products through a wholly-owned subsidiary, *Zicam*, LLC. One of the products sold during the Class Period was *Zicam* Cold Remedy, which was sold as a nasal spray and gel. The active ingredient in *Zicam* Cold Remedy was zinc gluconate.¹² Respondents alleged that *Zicam* Cold Remedy accounted for approximately 70 percent of *Matrixx*’s sales.¹³

During the Class period, *Matrixx* made a series of statements relating to revenues and product safety that respondents claimed were misleading in light of reports that *Matrixx* had received, but did not disclose, of users of *Zicam* who suffered anosmia (loss of sense of smell) after using the product.

¹¹ See Fed R. Civ. P. 12(b)(6), see also *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1959 (2009) (“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’”)

¹² *Matrixx*, 563 U.S. ____, at 2.

¹³ *Id.*

A. The Reports

In 1999, the neurological director of the Smell & Taste Research Foundation, Ltd., called Matrixx's customer to report that several of his patients had developed anosmia after using Zicam, including at least one that did not have a cold but nonetheless used Zicam and developed the condition. In 2002, Matrixx received a complaint from a user of Zicam who had developed anosmia, and contacted the user's treating physician at the University of Colorado Health Sciences Center. Timothy Clarot, Matrixx's vice president for research and development, informed the physician of similar complaints from other customers. The physician, Dr. Linschoten, informed Clarot that previous studies had linked zinc sulfate to the loss of smell. Clarot indicated that he was not aware of the studies, and also stated that Matrixx had not performed its own studies on Zicam, but had hired a consultant to review the product. Dr. Linschoten sent Clarot abstracts of the studies from the 1930's and 1980's that she had referred to, which confirmed zinc's toxicity. Clarot contacted Dr. Linschoten again to ask if she would participate in animal studies that Matrixx planned, but the physician declined.

In 2003, Dr Linschoten, in collaboration with Dr. Jafek from the University of Colorado (who had observed 10 patients that had developed anosmia after Zicam use), planned to present their findings to the American Rhinologic society in a presentation originally titled "Zicam Induced Anosmia", which presented the case study of a man who developed anosmia after using Zicam. The Society published an abstract prior to the meeting.¹⁴ Matrixx sent a letter to Dr. Jafek warning him that he did not have permission to use the name of Matrixx or the names of Matrixx products, prompting Jafek to delete references to Zicam in his presentation.

¹⁴ *Id.* at 4. See also "Conference Schedule of the American Rhinological Society, September 20, 2003", available at <http://app.american-rhinologic.org/programs/2003ARSFallProgram071503.pdf>.

Finally, by the end of the Class Period, nine plaintiffs had filed four products liability lawsuits against Matrixx, alleging that Zicam had impaired their sense of smell.¹⁵

B. The Alleged Misleading Statements

In October 2003, after Dr. Jafek's presentation to the American Rhinological Society, Matrixx stated that Zicam "was poised for growth in the upcoming cough and cold season" and that the company had "very strong momentum."¹⁶ Matrixx also stated that it expected revenues would "be up in excess of 50% and that earnings, per share for the full year [would] be in the 25 to 30 cent range."¹⁷ In January 2004, Matrixx estimated even higher residues, predicting an increase in revenues of 80 percent and earnings per share in the range of 33 to 38 cents.¹⁸

In Zicam's 10-Q filing with the SEC in November 2003, Zicam listed several materially adverse effects that could result from products liability actions, including a negative effect on Matrixx's "product branding and goodwill."¹⁹ However, it did not disclose that at least one product's liability suit alleging that Zicam caused anosmia had been filed.

On February 2, 2004, Matrixx responded to a Dow Jones Newswire report that stated that the FDA was "looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives, Inc. . . . may be causing some users to lose their sense of smell."²⁰ Matrixx's response, in the form of a press release, stated:

All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes

¹⁵ See, e.g., *Christensen v. Matrixx Initiatives, Inc.*, No. 03-cv-0146, Docket No 3. (W.D. Mich 2003); *Nelson v. Matrixx Initiatives, Inc., et al.*, No. YC048136 (Cal. Super. Ct. - Los Angeles); *Sutherland v. Matrixx Initiatives, Inc., et al.*, No. CV2003-1635-WHR (Ala. Cir. Ct. - Etowah); *Bentley, et al. v. Matrixx Initiatives, Inc., et al.*, No. CV2004-001338 (Ariz. Super. Ct. - Maricopa)

¹⁶ *Matrixx*, 566 U.S., at 4.

¹⁷ *Id.* at 5.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

statements alleging that intranasal Zicam products caused anosmia (loss of smell) are completely unfounded and misleading.

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.²¹

On the last day of the Class Period, February 6, 2004, Matrixx issued a substantially similar press release in response to a Good Morning America television segment that reported Dr. Jafek's findings, specifically that Dr. Jafek had discovered more than a dozen patients suffering from anosmia after using Zicam, and that four products-liability lawsuits had been filed against Matrixx.²² Following the Class Period, Matrixx made statements in an Form 8-K filing stating that it had convened a panel of doctors and scientists to review the current scientific evidence related to zinc gluconate's effect on users' sense of smell. Matrixx stated to a reporter a few weeks later that it would begin conducting human and animal studies on Zicam.

C. Procedural History

1. *The District Court Decision*

On April 27, 2004, respondents filed a class action against Matrixx and three directors and officers individually on behalf of investors who purchased Matrixx securities during the Class Period, alleging that the price of Matrixx common stock plummeted in response to the Dow Jones Report and *Good Morning America* segment, eventually incurring a one-day drop on the

²¹ *Id.* at 5-6, *see also* "Matrixx Initiatives Reaffirms Safety of Intranasal Zicam ® Cold Remedy", February 6, 2004, available at <http://integratir.com/newsrelease.asp?news=2130823539&ticker=MTXX>, (last visited March 27, 2011).

²² *Id.* at 6.

last day of the Class Period of 23.8% on unusually heavy trading volume.²³ The District Court for the District of Arizona dismissed the complaint without prejudice, stating that the allegations concerning adverse event reports were not material because they were not statistically significant, and further that plaintiffs had failed to sufficiently allege scienter.²⁴

The District Court went on to state that any amendment would be futile “[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was ‘sufficiently serious and frequent to affect future earnings.’”²⁵ The District Court relied on the standard used by the Second Circuit in *In Re Carter-Wallace, Inc. Securities Litigation* (“*Carter-Wallace I*”)²⁶ and *In re Carter-Wallace, Inc. Securities Litigation* (“*Carter-Wallace II*”)²⁷ in making its determination. In *Carter-Wallace I*, the Second Circuit held that the defendant drug-manufacturer’s failure to disclose deaths related to its drug was not materially misleading “until Carter-Wallace had information that Felbatol had caused a statistically significant number of . . . deaths and therefore had reason to believe that the commercial viability of Felbatol was threatened.”²⁸ *Carter-Wallace II* expanded this rationale to encompass the scienter requirement of 10b-5, stating that “it was not reckless for Carter-Wallace to consider the adverse event reports to be random. Not only were the financial statements not materially misleading before the link could be made, but any inference of scienter was negated as well.”²⁹

2. *The Ninth Circuit Decision*

²³ Siracusano, 585 F.3d at XXX

²⁴ *Id.*

²⁵ *Id.*

²⁶ 150 F.3d 153, 157 (2d Cir. 1998)

²⁷ 220 F.3d 36 (2d Cir. 200)

²⁸ 150 F.3d at 157.

²⁹ 220 F.3d. at 41.

The Ninth Circuit, however, rejected the adoption of the rule from *Carter-Wallace*, instead adhering to the rationale of *In Re Pfizer Inc. Securities Litigation*³⁰ and holding that a district court “cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact.”³¹ The Court then engaged in “the fact-specific inquiry required by *Basic*.”³² The Court concluded that the allegations made by the class were sufficient to allege materiality under § 10(b) and Rule 10b-5.

The Court then addressed the scienter requirement of the PSLRA, which requires that a complaint “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.”³³ A “strong inference” was defined in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.* as requiring that a “plaintiff alleging fraud under § 10(b) . . . must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference.”³⁴ Scienter has only been sufficiently plead if “a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”³⁵ If no one of the alleged statements, standing alone, creates a strong inference of scienter, the Court must “conduct a ‘holistic’ review” of all of the alleged misstatements, in order “to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness.”³⁶ Important to the Court’s decision was the 9th Circuit’s definition of deliberate recklessness, which included “an extreme departure from the standards of ordinary care.”³⁷ The Court, after review of the misleading statements listed above,

³⁰ 584 F.Supp. 2d 621 (S.D.N.Y. 2008)

³¹ *Siracusano*, 585 F.3d at X (quoting *In Re Pfizer*, 584 F.Supp at 635-36).

³² *Id.* at X

³³ 15 U.S.C. § 78u-4(b)(2)(2010).

³⁴ 551 U.S. 308, 310 (2007).

³⁵ *Id.*

³⁶ *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009).

³⁷ *In Re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999) (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990)(en banc)).

found that the holistic review of the complaint supported an inference of scienter that was “cogent and at least as compelling” as any “plausible non-culpable explanation.”³⁸ Specifically the Court stated that “[w]ithholding reports of adverse effects of and lawsuits concerning the product responsible for the company’s remarkable sales is ‘an extreme departure from the standards of ordinary care’ and ‘presents a danger of misleading buyers or sellers.’³⁹

3. *The Supreme Court Decision*

Perhaps curiously, the opinion in *Matrixx* spends most of its time discussing the materiality of the alleged misstatements or omissions. Not surprisingly, the Court declined to adopt a bright-line rule regarding statistical significance, stating that to adopt such a rule would “‘artificially exclud[e]’ information that “would otherwise be considered significant to the trading decision of a reasonable investor.”⁴⁰ The Court adopted the position of the SEC and other amici that statistical significance is not the only reliable measure of causation.⁴¹ “Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.”⁴² The Court stated that, perhaps unhelpfully, that the mere existence of adverse event reports, numbering *in toto* into the hundreds of thousands per year⁴³, does not compel disclosure; “something more is needed, but that something is not limited to statistical significance.”⁴⁴

³⁸ *Siracusano*, XXXX

³⁹ *Id.*, quoting *Tellabs*, 551 U.S. at 324.

⁴⁰ *Matrixx*, 563 U.S. at 11, quoting *Basic*, 485 U.S. at 236.

⁴¹ *Id.* at 11-12. The Court noted specifically that statistically significant data is not always available, that ethical considerations sometimes prevent researchers from conducting randomized clinical trials, and, perhaps most importantly for the member of the products liability defense bar, that medical experts rely on other evidence to establish an inference of causation. Defense attorneys looking for a bright-line rule in this case, ready to be plucked and exported to the next *Daubert* challenge, were undoubtedly disappointed, if unsurprised.

⁴² *Id.* at 15.

⁴³ See FDA, Safety Alerts for Human Medical Products,

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm196258.htm>.

⁴⁴ *Matrixx*, 561 U.S. at 16.

II. GENERAL PRINCIPLES: 10B-5 ACTIONS, PSLRA, TWOMBLY/IQBAL

Part Two of this paper will set forth the general legal principles that provide the backdrop for the *Matrixx* decision. In particular, the general federal pleading standards established in *Bell Atlantic Corp v. Twombly*⁴⁵, and *Ashcroft v. Iqbal*⁴⁶, will be contrasted with pleading standards established by the Private Securities Litigation Reform Act of 1995.⁴⁷ But before discussion of the specific pleading standards potentially affected by the *Matrixx* decision, a brief review of the required elements of a cause of action under § 10(b) of the Exchange Act and SEC Rule 10b-5 is necessary.

A. Elements of a Cause of Action under § 10(b) and SEC Rule 10b-5

Section § 10(b) of the Securities Exchange Act⁴⁸ makes it unlawful to employ any deceptive or manipulative device “in connection with the purchase or sale of any security.” Although the statute does not provide a private express cause of action for its violation, such a right has been routinely recognized by the federal courts.⁴⁹ SEC Rule 10b-5, promulgated pursuant to § 10(b), makes it unlawful:

- “(a) To employ any device, scheme, or artifice to defraud,
- (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
- (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.”⁵⁰

Prior to the intervention of Congress, the pleading standards for securities fraud were not governed by the general pleading standards of Federal Rule of Civil Procedure 8(a)(2), but by the

⁴⁵ 550 U.S. 544 (2007)

⁴⁶ 129 S.Ct. 1937 (2009)

⁴⁷ Securities Exchange Act of 1934, § 21D(b)(2), 15 U.S.C.A. § 78u-4(b)(2) (2010)

⁴⁸ 15 U.S.C. § 78(j)(b) (2010).

⁴⁹ See, e.g., *Herman & MacLean v. Huddleston*, 459 U.S. 375, 380 (1983).

⁵⁰ 17 CFR § 240.10b-5 (2010).

particularity requirements of Federal Rule of Civil Procedure 9(b), which requires that a plaintiff pleading common-law fraud “state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally”.⁵¹ However, in 1995, a legislative amendment to the Securities Exchange Act, the Private Securities Litigation Reform Act⁵² enacted §21(D), which set forth several requirements for plaintiffs pleading a cause of action under § 10(b). One requirement deals with the materiality requirement; the other with the scienter requirement.

As to materiality, § 21(D) requires that the plaintiff in the complaint in any private securities fraud action alleging material misstatements or omissions “specify each statement alleged to have been misleading; the reason or reasons why the statement is misleading; and if an allegation regarding the statement or omissions is made on information and belief, the complaint shall state with particularity all facts upon which that belief is formed.”⁵³ A court, in determining if the plaintiff has sufficiently alleged materiality, will consider the information “holistically”⁵⁴ of information in order to determine if there is “a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.”⁵⁵

As to scienter, the requirement is that, in any private action under the Exchange act in which the plaintiff “may recover money damages on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each such act or omission alleged to

⁵¹ Fed R. Civ. P. 9. See *Tellabs*, 551 U.S. at 319 (stating that, generally, “[p]rior to the enactment of the PSLRA, the sufficiency of a complaint for securities fraud was governed not by Rule 8, but by the heightened pleading standards set forth in Rule 9(b).”)

⁵² CITE

⁵³ CITE

⁵⁴ Basic Cite

⁵⁵ *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 439 (1976).

violate [the Exchange Act], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.”⁵⁶

The meaning of “strong inference” was left undefined by the PSLRA. However, it was clear that the intent of the PSLRA was to adopt a pleading standard stronger even than the Second Circuit’s existing pleading requirement, which was “[r]egarded as the most stringent pleading standard” then existing: “[b]ecause the Conference Committee intends to strengthen existing pleading requirements, it does not intend to codify the Second Circuit’s case law interpreting this standard.”⁵⁷

The Supreme Court considered the meaning of “strong inference” in *Tellabs, Inc v. Makor Issues & Rights, Ltd.*⁵⁸ The Court in *Tellabs* rejected the Seventh Circuit’s articulation of the term, stating that

[i]t does not suffice that a reasonable factfinder could plausibly infer from the complaint’s allegations the requisite state of mind. Rather, to determine whether a complaint’s scienter allegations can survive threshold inspection for sufficiency, a court governed by §21(D)(b)(2) must engage in a comparative evaluation; it must consider not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged. . . . To qualify as “strong” within the intendment of §21(D)(b)(2), we hold, an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.⁵⁹

Stating the requirement another way, the Court added that “A plaintiff alleging fraud in a § 10(b) action must plead facts rendering an inference *as least as likely* as any plausible opposing inference.”⁶⁰ This standard was the standard applied by the Court in *Matrixx* to the plaintiff’s scienter claims.

⁵⁶ CITE, note also that this pleading standard supersedes the federal pleading standard for pleading fraud actions, *see* Fed R. Civ. P. 9.

⁵⁷ Joint Explanatory Statement of the Conference Committee CITE

⁵⁸ *Tellabs* Cite

⁵⁹ *Id.*

⁶⁰ *Id.* at X

The PSLRA did not provide specific pleading standards for the remaining elements of a claim under §10(b). In general, federal courts applied either the liberal pleading standards of Federal Rule of Civil Procedure 8(a)(2) or the particularity requirements of Rule 9(b) to the other elements of such a claim.⁶¹ In recent years, a shift has occurred in general federal pleading standards due to the Court's holdings in *Twombly and Iqbal*. In light of this shift, the Court's holding in *Matrixx* casts serious doubt upon whether the pleading standards for materiality and scienter, rather than being the "most stringent" standards in federal pleading, have instead become the *easier* elements of a plaintiff's cause of action to plead satisfactorily.

B. *Twombly* and *Iqbal* alter the general federal pleading standard

Prior to *Twombly* and *Iqbal*,⁶² Federal Rule of Civil Procedure 8(a)(2), requiring that every complaint "contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief" was interpreted as require only "notice" pleading in federal complaints.⁶³ In the seminal case on the issue, *Conley v. Gibson*, the Supreme Court stated the "accepted rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."⁶⁴ The Court further elaborated that "all the Rules require is 'a short and plain statement of the

⁶¹ See, e.g., *In Re Mut. Funds. Inv. Litig.*, 566 F.3d 111, 119-20 (4th Cir. 2009) ("Congress only addressed misrepresentations[,][fraud] and scienter in [the PSLRA], the other elements of a securities fraud claim are analyzed under the Federal Rules of Civil Procedure . . . the PSLRA's heightened pleading requirements do not govern our analysis of reliance or loss causation."), see also *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 346 (holding that Federal Rule of Civil Procedure 8(a)(2) governs the sufficiency of a plaintiff's pleading of loss causation). See generally Jason N. Haycock, *Pleading a Loss Cause: Resolving the Pleading Standard for the Element of Loss Causation in a Private Securities Fraud Claim and a Plaintiff's Heavy Burden of Pleading it Under Iqbal*, 60 Am. U. L. Rev. 173 (2010).

⁶² Whimsically dubbed "Twiqbal" by some commentators.

⁶³ Fed R. Civ. P. 8(a)(2).

⁶⁴ 355 U.S. 41, 45-46 (1957).

claim’ that will give the defendant fair notice of what the plaintiff’s claim is and the ground upon which it rests.”⁶⁵

And such was the standard for the next half-century, with the Court rejecting any attempt by the lower federal courts to provide a heightened-pleading-standard gloss on the language of *Conley*.⁶⁶ Even *Dura Pharm.*, while appearing to establish a slightly higher standard for securities fraud plaintiffs in their pleading of loss causation, adhered to the language of *Conley* in its holding, stating only that a complaint that failed to allege that a share price, supposedly inflated by the defendants’ misrepresentations, fell after the truth was revealed, “failed [*Conley*’s] simple test.”⁶⁷

All of this changed with *Twombly* and *Iqbal*. In *Twombly*, the majority of the Court held that plaintiffs in an anti-trust action had not sufficiently alleged conduct indicative of a conspiracy among the various defendants to restrain trade in violation of the Sherman Act.⁶⁸ The Court stated that the Plaintiffs complaint, despite allegations of parallel conduct, did not contain “enough facts to state a claim for relief that [wa]s plausible on its face.”⁶⁹ The Court explicitly rejected the language of *Conley*, stating that *Conley*’s “no set of facts” language “has earned its retirement” and “is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of

⁶⁵ *Id.*

⁶⁶ See, e.g. *Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit*, 507 U.S. 163 (1993), and *Swierkiewicz v. Sorema*, 534 U.S. 506 (2002).

⁶⁷ *Dura Pharm.*, 544 U.S. at X

⁶⁸ 550 U.S. at 551.

⁶⁹ *Id.* at 570.

facts consistent with the allegations in the complaint.”⁷⁰ The Court articulated the new standard as requiring plaintiffs to “nudge[] their claims across the line from conceivable to plausible”⁷¹

After *Twombly*, some commentators expressed the hope or belief that the holding would be confined to anti-trust cases, whose complexity, perhaps, demanded a heightened pleading standard in order to sort the strike suits from the valid ones.⁷² However, *Iqbal* made it clear that the Court’s “decision in *Twombly* expounded the pleading standard for ‘all civil actions.’”⁷³

Iqbal involved a *Bivens* action for violation of the First and Fifth Amendments to the U.S. Constitution.⁷⁴ The Court in *Iqbal* expanded upon the line, enunciated in the footnote of *Twombly*, between the conclusory and the factual, stating that pleadings that “are no more than conclusions[] are not entitled to assumption of truth.”⁷⁵ The Court thus separated conclusory allegations from allegations it found sufficiently grounded in fact before conducting an analysis of the complaint’s plausibility under *Twombly*.⁷⁶ The Court concluded the plaintiff’s complaint, stripped of its “conclusory” allegations, did not “state a plausible entitlement to relief for unconstitutional discrimination.”⁷⁷

In summary, the pleading standard for complaints plead under Federal Rule of Civil Procedure 8(a)(2) requires that the plaintiff’s allegations first be grounded in facts rather than conclusory, and second that those allegations are plausible, rather than merely conceivable.⁷⁸ Since this standard debuted, it almost immediately resulted in numerous products liability

⁷⁰ *Id.* at 563.

⁷¹ *Id.* at 570. The court also suggested in a footnote that, in addition to the line between the conceivable and the plausible, a plaintiff’s allegations in the complaint must also cross “the line between the conclusory and the factual.” *Id.* at 557 n.5

⁷² See Adam N. Steinman, *The Pleading Problem*, 62 *Stan. L. Rev.* 1293, 1295; see also Stephen R. Brown, *Reconstructing Pleading: Twombly, Iqbal, and the Limited Role of the Plausibility Inquiry*, 43 *Akron L. Rev.* 1265, 1278 (2010).

⁷³ *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1953 (2009) (quoting Fed R. Civ. P. 1).

⁷⁴ See *Bivens v. Six Unknown Federal Narcotics Agents*, CITE; *Iqbal*, 129 S.Ct. at 1948.

⁷⁵ *Id.* at X

⁷⁶ *Id.* at 1950-52.

⁷⁷ *Id.* at 1952.

⁷⁸ See Brown, *supra* note 72, at 1283.

complaints and class actions against, among others, drug manufacturers being dismissed at the pleading stage for lack of plausibility.⁷⁹

But how does the Court's decision in *Matrixx*, dealing as it does with the specific pleading requirements of the PSLRA, relate to the new *general* pleading standard enunciated by the Court in *Twombly & Iqbal*. The next Part of this paper will discuss the *Matrixx* decision itself, and how the Court appears to have rendered the pleading requirement for materiality and scienter *easier* for plaintiffs to meet than if the *Twombly/Iqbal* standard were applied.

III. THE *MATRIX* DECISION AND ANALYSIS

At first blush, the *Matrixx* decision appears not to add much to the area of securities fraud jurisprudence. After all, the Court expressly declined to adopt a new rule governing materiality and statistical significance, instead falling back on the same materiality inquiry articulated in *TSC* and *Basic*.⁸⁰ But a close reading of the Court's stated reasons for its holding reveals that the Court, deliberately or unconsciously, may in fact be "watering down" the pleading standard articulated by the PSLRA, and that a current analysis of the standard compared to the *Twombly/Iqbal* standard reveals that, far from being the most stringent standard in federal pleading, the requirements for pleading materiality and scienter may actually be *easier* to satisfy than the general federal pleading requirements under Rule 8, at least in the context of suits against drug manufacturers.

A. The Decision

⁷⁹ See, e.g., *In re Bausch & Lomb Inc.*, 2007 WL 3046682 (D.S.C. Oct. 11, 2007), *Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628 (D.N.J. Jan. 14, 2008), *Sykes v. Bayer Pharmaceuticals Corp.*, 548 F. Supp.2d 208 (E.D. Va. Feb. 12, 2008), *Heck v. American Medical Systems, Inc.*, 2008 WL 1990710 (D. Md. April 30, 2008), *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965 (S.D. Ohio June 17, 2008), *Wolicki-Gables v. Arrow International, Inc.*, 2008 WL 2773721 (M.D. Fla. June 17, 2008), *Adkins v. Cytoc Corp.*, 2008 WL 2680474 (W.D. Va. July 3, 2008), *Heisner v. Genzyme Corp.*, 2008 WL 2940811 (N.D. Ill. July 25, 2008), *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. Appx. 597 (11th Cir. July 29, 2008), *Simmons v. Stryker Corp.*, 2008 WL 4936982 (D.N.J. Nov. 17, 2008), *Horowitz v. Stryker Corp.*, 613 F. Supp.2d 271 (E.D.N.Y. Feb. 20, 2009).

⁸⁰ *Matrixx*, 563 U.S. at 19

1. *Materiality Heading*

The alleged misstatements and/or omissions plead in the class’s master complaint are listed in Part I of this paper⁸¹. Interestingly, despite the fact that materiality has its own pleading requirement, the Court referenced both *Twombly* and *Iqbal* in its reasoning, saying that it believed “that these allegations suffice to ‘raise a reasonable expectation that discovery will reveal evidence’ satisfying the materiality requirement, and to ‘allo[w] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”⁸²

The Court appeared to be engaging in the first part of a *Twombly/Iqbal* analysis of a pleading plead under Rule 8, that of identifying conclusory allegations and factual allegations in the complaint. However, it also stated that “[v]iewing the allegations of the complaint as a whole” plaintiffs had alleged facts suggesting a significant risk to the commercial viability of Zicam.⁸³ The Court did not appear to engage in the kind of division into conclusions and factual allegations that *Iqbal* requires. In fact, the Court’s only other reference to *Iqbal* comes at the beginning of the opinion, where it simply states that “[r]espondents’ consolidated amended complaint alleges the following facts, which the courts below properly assumed to be true” followed by a citation to *Iqbal*.⁸⁴ This statement could be read as a statement that the Court was not performing a conclusory/factual analysis because the Ninth Circuit or the District Court already did so.

The Ninth Circuit explicitly *did not* perform the sort of analysis required by *Twombly/Iqbal* (*Iqbal* being at the time slightly less than 2 months old). The court specifically stated that “[i]n review the district court’s dismissal for failure to state a claim, we accept the plaintiff’s

⁸¹ See supra Part I pp X-X

⁸² *Matrixx*, 563 U.S. at 18, quoting *Twombly*, 550 U.S. at 556, and *Iqbal*, 556 U.S. at ____ (slip op., at 14).

⁸³ *Id.* at 18-19.

⁸⁴ *Id.* at 3.

allegations as true and construe them in the light most favorable to the plaintiffs.”⁸⁵ The District Court, further, did not apply *Twombly* or *Iqbal* for the simple reason that neither case had been decided at the time.⁸⁶

Neither court, nor the Supreme Court, was required to apply *any* rule 8 standard to plaintiffs’ allegations of material misstatements or omissions. Why then, is the Supreme Court taking pains to state that the allegations of the plaintiffs satisfy *Twombly* and *Iqbal*? Especially because, unlike a complaint that has been vetted by a court under *Iqbal* and stripped of conclusory allegations, the Court in *Matrixx* explicitly assumed all of the complaint’s allegations to be true.⁸⁷ The District Court noted that the Plaintiff’s failed to allege that “during the class period, Defendants were presented with any evidence that the University of Colorado study was reliable, the methodology used, or that it was subject to peer review” and also appears to be the only Court to give any weight to the fact that defendant “conducted a double-blind study regarding Zicam and not a single case of anosmia was reported.”⁸⁸ It is at least possible that a court analyzing some of the allegations taken as true by the Court, in conducting an analysis into each statements conclusory or factual nature, could find some of them to be conclusory, especially in light of a failure to allege specific details about the nature of the studies finding a link between anosmia and Zicam. After all, in *McAdams v. McCord*⁸⁹ illustrates how, in the words one commentator, “the distinction between legal conclusion and factual allegation is generally a matter of specificity and is difficult to distinguish.”⁹⁰

⁸⁵ *Siracusano II*, CITE at page n 2

⁸⁶ *Siracusano I*, 2005 WL 3970117, at *4 (D. Ariz. 2005).

⁸⁷ *Matrixx* Cite

⁸⁸ *Siracusano I* at *7

⁸⁹ 584 F.3d 1111 (8th Cir. 2008)

⁹⁰ Jason Haycock, *Pleading a Loss Cause: Resolving the Pleading Standard for the Element of Loss Causation in a Private Securities Fraud Claim and a Plaintiff’s Heavy Burden Pleading it Under Iqbal*, 60 Am. U. L. Rev. 173 (2010).

In *McCord*, the Eighth Circuit, considering an appeal from a District Court dismissal of a securities fraud action for failure to sufficiently plead materiality and scienter, exercised its discretion to affirm the District Court on any basis supported by the record, and affirmed on the basis that the plaintiffs had not adequately plead the element of loss causation under Rule 8(a)(2).⁹¹ The plaintiffs, investors in the defendant company, alleged that the defendant outside auditor made two statements that misrepresented the company's overall financial condition, and that the plaintiffs were damaged when the truth emerged regarding the company's condition when the company revised several financial statements. The court found that the plaintiffs had failed to "state the value of UCAP's stock when the investors made their investments, or its value right before, or right after, the need for the restatement was announced."⁹² The lack of this information rendered the allegation "conclusory" in the court's eyes.⁹³

The Court in *Matrixx* clearly, despite lip service to *Twombly* and *Iqbal*, performed a very different type of analysis in determining the materiality of the alleged misstatements of *Matrixx*. Which, of course, is appropriate, considering that expressly different pleading standards apply to materiality and scienter than the other elements of a § 10(b) claim. Having concluded that the plaintiffs satisfied the requirement of alleging material misrepresentations or omissions, the Court then concluded that a reasonable investor would have found the information significant. The Court noted, based on its earlier reasoning that *Matrixx* was plausibly informed of a link between Zicam and anosmia, that "Matrixx had information indicating a significant risk to its leading revenue-generating product" and that *Matrixx*'s statements to the public had omitted "evidence of a biological link between Zicam's key ingredient and anosmia" and that it had not

⁹¹ *McCord*, 584 F.3d at 1115

⁹² *Id.*

⁹³ *Id.*

“conducted any studies of its own to disprove the link.”⁹⁴ The Court concluded that the above-mentioned facts were “material facts ‘necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.’”⁹⁵

The *Iqbal* test and the PSLRA test for materiality seem to share a similar bipartite structure. The first prongs of both tests seem to operate similarly—under *Iqbal* the plaintiff is required to plead sufficient factual content, whereas under the PSLRA and Rule 9 a plaintiff is required to plead “factual particularity.” There appears to be no meaningful analytical distinction between the two first prongs when viewed from this level.⁹⁶

However, in light of the fact that the PSLRA standard is supposed to be “heightened”, it appears surprising that it may be easier for a plaintiff to satisfy the PSLRA standard than the *Iqbal* test. Had the alleged misstatements and omissions in *Matrixx* been considered under *Iqbal*, with each allegation considered separately to determine if it was based in fact or merely conclusory, some of the allegations may have been viewed as conclusory and stricken from the Court’s analysis in the second prong. But under the rules of *TSC* and *Basic*, the Court considered the *Matrixx* allegations holistically, taking *all* allegations as true without this sort of analysis taking place.

Satisfying the second prong of *Iqbal*, plausibility, may prove significantly harder than satisfying the test for materiality from *TSC* and *Basic*. Particularity in pleading is a necessary,

⁹⁴ *Matrixx*, 563 U.S. ____ (slip op. at 19). The Court appeared to give no weight to *Matrixx*’s studies that had *failed to find* any evidence of anosmia in Zicam users, but found it significant that *Matrixx* had not, during the class period, conducted any further studies in light of the information it had. This statement raises interesting implications on its own for drug manufacturers. Randomized, double-blind studies are expensive and time-consuming. It would seem logical that a company, when deciding to study the causal link between a reported adverse effect and use of its product, would use some sort of threshold mechanism to decide if the study was worth the time and expense; if not statistical significance, then what should the manufacturer use? An additional interesting hypothetical, somewhat outside the scope of this paper, is this: what would have happened if *Matrixx* had conducted the studies and found that, while some users reported anosmia, this effect did not rise to the level of statistical significance within the experiment, and had stated to the public that “*Matrixx* has conducted a double-blind trial and found no reliable evidence that Zicam causes anosmia?”

⁹⁵ *Id.* quoting 17 C.F.R. § 240.10b-5(b).

⁹⁶ See Haycock, *supra* note 90, at 204-205.

but not sufficient, precursor to plausibility. To use the example of loss causation, a court may be willing to consider alternative plausible explanations for a plaintiff's loss, and that a pleading of loss causation must not only be plausible, but at least as plausible as alternative explanations.⁹⁷ Since there are often a multitude of factors that have potential impact on an individual's loss, it can be difficult to point to a particular misstatement or omission as the cause of that loss.⁹⁸ It is at least possible that a plaintiff could have a harder time clearing the hurdle of *Iqbal's* second prong than he or she would have in convincing a court that a reasonable investor would have found the missing or misrepresented information relevant.

B. Scierer Heading

The Court in *Matrixx* dealt with the defendant's contention that plaintiff's had not adequately alleged facts sufficient to support the "strong inference" that it acted recklessly or knowingly with respect to the alleged misrepresentations. Not surprisingly, the Court rejected a bright-line rule that an allegation of statistical significance is required to establish such an inference.⁹⁹ It also rejected the defendant's proposal that "the most obvious inference is that petitioners did not disclose the [reports] simply because petitioners believed they were far too few . . . to indicate anything meaningful about adverse reactions to use of Zicam."¹⁰⁰ This response may have been due to the cursory way that *Matrixx* itself argued that the plaintiffs had failed to sufficiently allege scierer; the Brief for Respondents devotes just two pages to the issue.¹⁰¹

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⁹⁷ Haycock, *supra* note 90, at 207.

⁹⁸ See Jill E. Fisch, *Cause for Concern: Causation and Federal Securities Fraud*, 94 Iowa L. Rev. 811, 821 (2009)(stating that proving loss causation in the securities fraud context is particularly difficult because of the many factors that can affect the value of a security).

⁹⁹ *Matrixx*, 563 U.S. (slip op. at 13).

¹⁰⁰ *Id.*

¹⁰¹ Brief for Respondents, pp 49-51.

The Court appears to draw the inference from Matrixx's actions concerning statements being made about its product: "[t]hese allegations, 'taken collectively' give rise to a 'cogent and compelling' inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market."¹⁰² This is interesting, because it would seem that the inference at issue was whether or not Matrixx believed that the reports actually indicating anything meaningful about adverse reactions to Zicam. It seems logical that a company might feel compelled to respond to even groundless statements in the marketplace concerning its products, irrespective of its belief in the reliability of any negative reports it has received.

The Court further seemed to place great weight on the actions taken by Matrixx to investigate the information it had received: "Matrixx was sufficiently concerned about the information it received that it informed Linschoten that it had hired a consultant to review the product, asked Linschoten to participate in animal studies, and convened a panel of physicians and scientists in response to Dr. Jafek's presentation."¹⁰³ There appear to be two plausible inferences that could be drawn from the above information: one, that Matrixx investigates complaints about its products and attempts to gather scientific data to determine if there is actually a problem before disclosing information, or two, that Matrixx attempted to discredit the reports with statements in the marketplace regardless of their truth. One of Matrixx's *amici*, the Washington Legal Foundation, noted this very fact, stating that "the most cogent inference . . . is that [Matrixx] delayed releasing information regarding anosmia complaints in order to provide itself an opportunity to carefully review all evidence regarding any link between Zicam and

¹⁰² *Matrixx*, 563 U.S. (slip op. at 22).

¹⁰³ *Id.* at 22.

anosmia.”¹⁰⁴ The Court dealt with this opposing inference cursorily, saying that while touch an inference may be the most cogent inference in some cases, the “misleading nature of Matrixx’s press release” was sufficient to render the inference of scienter at least as compelling as the alternative inference.¹⁰⁵

However, what exactly was misleading about the press release? The Court faults Matrixx for making the statement that “suggested” that scientific studies had confirmed Zicam did not cause anosmia when it had not conducted any studies on the Zicam-anosmia link and the current state of the scientific evidence was insufficient to determine if a causal link in fact existed.¹⁰⁶ But Matrixx reported that two clinical trials had not show links to anosmia, not that it had specifically designed its studies to determine a causal connection between Zicam and anosmia. *After the class period ended*, Matrixx convened a panel of scientists to determine the current state of the scientific evidence on smell disorders, and upon learning that in the opinion of that panel there was insufficient evidence to determine if zinc gluconate use was linked to anosmia, it filed a Form 8-K with the SEC making that same statement.¹⁰⁷

The Court did not specifically mention it, but the Ninth Circuit found fault with Matrixx for issuing the February 2, 2004 press release containing the statement “ Matrixx believes *statements alleging that intranasal Zicam products caused Anosmia . . . are completely unfounded and misleading.*”¹⁰⁸ The court said that the release was inaccurate because by that date, it could be strongly inferred that Matrixx knew that “the statements alleging a link a between Zicam and anosmia were not ‘completely unfounded and misleading.’”¹⁰⁹ But that is not

¹⁰⁴ Washington Legal Foundation Amicus Brief pp26

¹⁰⁵ *Matrixx*, 563 U.S. ____ (slip op. at 21 n 15)

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 7, see also SEC Form 8-K, 2/17/04, available at

<http://www.sec.gov/Archives/edgar/data/1006195/000095015304000379/0000950153-04-000379-index.htm>

¹⁰⁸ Ninth Circuit Cite (emphasis added)

¹⁰⁹ *Id.*

what Matrixx said. Rather it stated that the statements alleging that Zicam was the *cause* of anosmia were completely misleading and unfounded. The Ninth Circuit also characterized the statement that Matrixx was “not aware of an FDA inquiry” as denying that the FDA was investigating Zicam.¹¹⁰

All of the Ninth Circuit’s reasoning, or part, or none, may have informed the Court’s characterization of the press release as “misleading.” The point is simply this: Matrixx made a series of statements, none of them obviously untrue at the time they were made, and all of which were susceptible to an inference of innocent as well as guilty behavior. Added to this is the obvious fact that this opinion had yet to be written, and *Carter-Wallace I & II* were available to support the idea that Matrixx felt it had no duty to disclose the adverse event reports absent statistical significance. In fact, recent caselaw recognizes that a drug and device manufacturer that delays in addressing adverse reports while conducting studies to confirm the information acts prudently, rather than deceptively.¹¹¹

The *Tellabs* standard requires that the inference of scienter be “at least as compelling as any opposing inference one could draw from the facts alleged.”¹¹² In the case of equal-strength opposing influences, the tie goes to scienter. How would these allegations have fared if analyzed under the *Twombly/Iqbal* pleading framework of Rule 8?

C. The Complaint in Matrixx may have failed the plausibility analysis required by *Twombly* and *Iqbal*

¹¹⁰ *Id.*

¹¹¹ See, e.g., *In Re Medtronic Inc. Sec. Litig.*, 618 F. Supp. 2d. 1016, 1036 (D. Minn. 2009)

¹¹² 551 U.S. at 323-24.

The pleadings in *Twombly*, once the Court had discounted the “few stray statements that sp[oke] directly of an agreement [to restrain trade] as “merely legal conclusions” alleged conduct on the part of the defendant companies that could have been the result of either parallel conduct or an agreement to restrain trade.¹¹³ The Court, in dealing with each allegation, stated its belief that each of the defendants’ alleged conspiratorial actions could have been explained by lawful, independent goals rather than by a conspiracy. The opinion is replete with phrases such as “natural, unilateral reaction to each [defendant] intent on keep its regional dominance”, “there is no reason to infer that the [defendants] had agreed among themselves to do what was only natural anyway” and in fact that the behavior was *so* natural that to allow the plaintiff’s allegations to suffice would insure that “pleading a [Sherman Act] violation against almost any group of competing businesses would be a sure thing.”¹¹⁴

The court noted the “obvious alternative explanation” that the companies independently chose not to compete as dictated by economic pressures rather than by conspiracy.¹¹⁵ The plaintiff in *Twombly*, of course, failed to “nudge their claims across the line from conceivable to plausible.”¹¹⁶ It appears from the analysis of the plaintiffs allegations conducted by the Court, however, that this “nudge” did not occur because, at least in part, of alternate inferences that could be drawn from the facts alleged.

Similarly, the *Iqbal* Court considered plausible alternate explanations when considering the essentially redacted (because stripped of “conclusory” allegations) complaint before it. The Court concluded that plaintiffs had not alleged that the defendants had purposefully adopted a policy of classifying post-September-11 detainees as “of high interest” because of their race,

¹¹³ 550 U.S. at 564.

¹¹⁴ *Id.* at 566.

¹¹⁵ *Id.* at 568.

¹¹⁶ *Id.*

religion, or national origin, in light of an “obvious alternate explanation” that “the Nation’s top law enforcement officers, in the aftermath of a devastating terrorist attack, sought to keep suspected terrorists in the most secure conditions available until the suspects could be cleared of terrorist activity.”¹¹⁷

It is at least possible that a court applying the framework of *Twombly* and *Iqbal* would have come to the conclusion that the plaintiffs pleading of scienter in *Matrixx* did not pass muster. Although the *Iqbal* Court stated that it was applying a pleading standard that was “less rigid” than the Rule 9(b) particularity standard, it is not at all clear that the standard is actually less rigid as applied.¹¹⁸ Justice Souter, who wrote the *Twombly* opinion, dissented in *Iqbal*. His principal complaint with the majority’s reasoning was that the factual statements that were dismissed as “conclusory” were read in isolation, rather than in the context of the complaint as a whole.¹¹⁹ Justice Souter noted the *Twombly* Court interpreted the complaint before it as a whole and only excluded from the analysis those statements that were restatements of allegations found elsewhere in the complaint, that did not add new facts to the complaint.¹²⁰ The *Iqbal* Court also provided no guidance for the determination of which allegations were conclusory.¹²¹

The *Tellabs* standard applied by the Court in *Matrixx* makes it clear that “the court’s job is not to scrutinize each allegation in isolation but to assess all the allegations holistically.”¹²² This stands in marked contrast to the *Twombly/Iqbal* approach of first analyzing the allegations individually to determine their factual or conclusory nature and then conducting a plausibility

¹¹⁷ *Iqbal*, 129 S.Ct. at 1952.

¹¹⁸ *Id.* at 1954.

¹¹⁹ *Id.* at 1960-61 (Souter, J., dissenting).

¹²⁰ *Id.*, see also Haycock, *supra* note 90, at 204.

¹²¹ See Robert G. Bone, *Plausibility Pleading Revisited and Revised: A Comment on Ashcroft v. Iqbal*, 85 Notre Dame L. Rev. 849, 862-99 (arguing that a notice pleading system has no need for a distinction between legal conclusions and factual allegations because the proper analysis is whether the complaint, taken as a whole, gives fair notice of what the dispute was about).

¹²² *Tellabs*, CITE

analysis. Besides this, lower Courts following the lead of *Twombly* and *Iqbal* have shown their willingness to grant motions to dismiss when an alternate explanation exists that is *as plausible* as the allegation of wrongful conduct.¹²³

Simply put, the complaint at issue in *Matrixx* may well have failed to survive a motion to dismiss under Rule 8(a)(2), despite surviving under the so-called “heightened” requirements of Rule 9(b) and the PSLRA. To begin with, the complaint, rather than being viewed as a totality, would have had each allegation separately analyzed to determine whether it was conclusory or factual. Although the factual statements concerning *Matrixx*’s statements in the marketplace would obviously survive this prong, the totality of the complaint may well have been altered. Following this, it would seem possible that a court could conclude, in light of strong alternative inferences, that the plaintiffs had not plausibly alleged either materiality or scienter. The inference is available, for example, that a reasonable investor would not find a handful of adverse event reports significant; after all, the FDA itself cautions against using “raw” (not statistically analyzed) adverse event reports to determine scienter.¹²⁴

But perhaps the materiality allegations would have sufficed under Rule 8. After all, the Court stated that the facts alleged in the complaint plausibly suggested that the conclusions drawn by Dr. Jafek and Linschoten’s conclusions were based on reliable evidence of a causal

¹²³ See *Adkins v. Cytyc Corp.*, 2008 WL 2680474 (W.D. Va. July 3, 2008), at *2 (stating that “Where there are two explanations for the damages complained of within the four corners of the Complaint, one of which would allow recovery if true and the other of which could not allow any recovery due to preemption, a plaintiff has failed to state a claim for relief if she has not given any facts to make it more plausible that it was the former rather than the latter); *Gonzalez v. Bristol-Meyers Squibb Co.*, 2009 WL 521984, at *6 (denying plaintiff’s negligent misrepresentation claim under Rule 8 for failing to plead factual allegations sufficient to allege, at a minimum, the reliance element of plaintiff’s claim.)

¹²⁴ See FDA, Center for Drug Evaluation and Research, *Annual Adverse Event Drug Experience Report: 1996 2* (Oct. 30, 1997) (stating that “[a]ccumulated [adverse events] may not be used to calculate incidences or estimates of drug risk. Numbers from these data should be care-fully interpreted as reporting rates and not occurrence or incidence rates.”)

link between Zicam and anosmia.¹²⁵ But again, this conclusion was made from viewing the complaint as a whole.

Notwithstanding a finding of materiality, a court analyzing the scienter allegations under the Rule 8(a)(2) pleading standard could easily have dismissed the complaint for failing to plausibly allege this element. The inference that Matrixx delayed releasing information about anosmia until it had reviewed all of the evidence is a strong one; so too is the inference that, in light of the lack of statistical significance and existing precedent (both judicial and FDA-promulgated) at the time of the complaint, Matrixx thought the information was non-material, speculative, or inconclusive, and thus not requiring disclosure.¹²⁶ These inferences could well be “obvious alternative explanations” sufficient to defeat a plaintiff’s claim under *Twombly* and *Iqbal*.

CONCLUSION

The Court’s decision in *Matrixx* may signify a watering-down of the heightened standards for the pleading of materiality and scienter in §10(b) actions; at the very least, it indicates that a drug manufacturer is not safe from suit by its investors because the adverse event reports it has received are not statistically significant. But this decision, viewed in comparison with the application of general federal pleading standards under *Twombly* and *Iqbal*, raises the question: is the pleading standard for 10(b) actions, whether watered-down by the Court in *Matrixx* or not, any higher than the general pleading standard? It appears that it may actually be *easier* for an investor who has lost money in a drug manufacturer’s securities to survive a motion to dismiss on his suit than it is for a person injured by that same manufacturer’s products to bring suit, because the investor enjoys having his complaint analyzed as a whole and wins if the

¹²⁵ *Matrixx*, 563 U.S., slip op. at 17 fn 12.

¹²⁶ *Basic*, 485 U.S. at 231 (quoting *TSC Indus.* 426 U.S. at 448) (“Information need not be disclosed that is inconclusive, speculative, or ‘of dubious significance.’”).

competing inferences tie, whereas the injured person will have his each allegation scrutinized in isolation, and then have a redacted version of his complaint analyzed in such a way that a competing inference of innocent behavior may well defeat his claim.

The Court's decision in *Matrixx* may well lead to less dismissals at the pleading stage of § 10(b) claims against drug manufacturers or defendants who rely (or claim to rely) on statistical significance in determining whether to disclose information to investors. At the very least, it strips defendants of the defense of statistical insignificance. More broadly, it suggests that perhaps the heightened pleading standards of the PSLRA are no longer higher than the general federal pleading burden, and may even, perhaps, be lower.