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MARCIE BRECHER*

Matrixx Initiatives, Inc. v. Siracusano: Nasal Spray Decision Throws Corporations Off the Scent of “Materiality” Definition

IN *MATRIXX INITIATIVES, INC. v. SIRACUSANO*,¹ THE UNITED STATES SUPREME COURT considered whether a plaintiff bringing a securities fraud claim under the Securities Exchange Act Section 10(b)² and Securities Exchange Commission (“SEC”) Rule 10b-5³ must allege that a pharmaceutical company’s undisclosed adverse event reports are statistically significant.⁴ Citing *Basic Inc. v. Levinson*,⁵ the Court held that materiality turns on whether a reasonable investor would consider the undisclosed information to have “significantly altered the ‘total mix’ of available information,” stating that, while statistical significance is not required, “something more” than allegations of adverse events alone is necessary.⁶ The Court’s “something more” standard makes it difficult for business entities to ascertain materiality, and consequently, to know when a duty to disclose is triggered and for courts to treat similarly situated defendants comparably.⁷ The Court’s silence on how to apply the standard across industries may initiate unnecessary disclosures of non-material information, hindering an investor’s informed decision-making.⁸

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* J.D. Candidate 2012, University of Maryland Francis King Carey School of Law. I would like to thank my parents for their unwavering support and my journal colleagues for their invaluable comments and feedback.

1. 131 S. Ct. 1309 (2011).

2. 15 U.S.C. § 78j (2006).

3. 17 C.F.R. § 240.10b-5 (2010).

4. 131 S. Ct. 1309, 1313 (2011). An adverse event is defined by the Food and Drug Administration as “[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related . . .” 21 C.F.R. § 314.80 (a) (2010). Statistical significance is generally stated as a five-percent standard deviation from the norm, but the percentage may differ by specific circumstances. David H. Kaye, *Trapped in the Matrixx: The U.S. Supreme Court and the Need for Statistical Significance*, 11 Expert Evidence Rep. (BNA) No. 494, at 2 (Oct. 24, 2011) (noting that a p-value of 0.05 “ensures that inferring that something other than randomness is at work when, in fact, randomness is all there is to it occurs no more often than 1 time in 20 (in the long run)”).

5. 485 U.S. 224 (1988).

6. *Matrixx*, 131 S. Ct. at 1318–23. See also *infra* Part III.

7. See *infra* Part IV.

8. See *infra* Part IV.

I. THE CASE

A. Factual Background

Zicam, LLC, a wholly owned subsidiary of Matrixx Initiatives, Inc., manufactures over-the-counter, homeopathic common cold remedies, including Zicam nasal spray and gel swabs.⁹ From 1999 to 2003, Matrixx sold millions of Zicam products and received between twelve and twenty-three adverse event reports of anosmia—a permanent or temporary loss of sense of smell—following the use of Zicam nasal gel or spray.¹⁰ Early adverse event reports of anosmia came from three sources: Dr. Alan Hirsch, Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd.; Miriam Linschoten, Ph.D., of the University of Colorado Health Sciences Center; and Dr. Bruce Jafek of the University of Colorado School of Medicine.¹¹ On October 14, 2003, Zicam users filed the first of four lawsuits during the class period, alleging anosmia following Zicam use.¹²

Matrixx projected positive earnings expectations in 2003 and early 2004 on the strength of the Zicam family of products, failing to disclose several pending lawsuits in conversations with investors and the public.¹³ Matrixx's 2003 SEC 10-Q filing in November mentioned the possibility of significant costs associated with future products liability lawsuits, but did not mention the lawsuit brought in mid-October 2003.¹⁴ In response to two negative news articles in early 2004, Matrixx denied any connection between Zicam products and anosmia.¹⁵ Matrixx instead asserted that

9. *Siracusano v. Matrixx Initiatives, Inc.*, No. CV 04 0886 PHX MHM, CV 04 1012 PHX MHM, 2005 WL 3970117 at *1 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011).

10. *Id.* at *1–3. The exact number of adverse event reports was disputed. *Id.* at 3. In 2002, a Matrixx VP stated that the company had not conducted any studies, but had “hired a consultant to review the product.” *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1170 (9th Cir. 2009).

11. Both Hirsch and Linschoten reported one patient who experienced anosmia after Zicam use and pointed Matrixx to earlier studies linking zinc to anosmia when applied intranasally. *Siracusano*, 585 F.3d at 1170. Jafek presented findings to the American Rhinologic Society that ten users of nasal gel, experienced “an immediate, severe burning” and suffered a loss of smell. *Id.* at 1171. Matrixx denied Jafek’s request for permission to name Zicam in the presentation. *Id.* During the class period, companies were not required to report serious side effects from over-the-counter homeopathic drug use to the Food and Drug Administration. Brief for Petitioner at 18 *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09–1156), 2010 WL 3334501 at *18.

12. *Siracusano*, 585 F.3d at 1175.

13. *Id.* at 1171–73. On October 22, 2003, Matrixx announced third quarter net sales of 163% over third quarter 2002 and later upwardly revised FY03 revenue expectations by 80% compared to FY02 on Zicam sales. *Id.* at 1171. The following day, when Matrixx officers were asked to comment on any pending litigation involving Matrixx or its officers, they denied the litigation and any knowledge about an SEC investigation. *Id.* at 1172. Matrixx was served with the first lawsuit on October 23, 2003, the day of the earnings conference call, and there is no evidence that the comment was corrected by officers of the corporation thereafter. *Id.* at 1172. Three additional lawsuits were filed against Matrixx on December 8, 2003, December 18, 2003, and January 23, 2004. *Id.* at 1175. The plaintiffs claimed these misstatements violated Generally Accepted Accounting Principles because these lawsuits raised questions regarding the product safety of a core line of products. *Id.*

14. *Id.* at 1172.

15. *Id.* at 1172–75. In late January and early February 2004, the *Dow Jones Newswires* and *Good Morning America* issued back-to-back reports, disclosing that Zicam was under scrutiny by the FDA and that Matrixx

“two double-blind, placebo-controlled, randomized clinical trials” affirmed that the active ingredient, zinc gluconate, was safe and effective in treating common cold symptoms.¹⁶ On February 19, 2004, however, Matrixx stated that the data linking the intranasal application of zinc gluconate to anosmia were inconclusive and that further study would be undertaken regarding potential causation.¹⁷ Investors who had purchased thousands of Matrixx shares between October 22, 2003 and February 6, 2004 filed a securities fraud class action claim against Matrixx and three Matrixx executives, alleging that the corporation made materially false and misleading statements about Zicam Cold Remedy products.¹⁸

B. Procedural History

The U.S. District Court of Arizona held the plaintiff had not made a prima facie showing of either materiality or scienter, the first two elements in a securities fraud claim, and granted the defendant’s motion to dismiss.¹⁹ The court concluded that statements by Matrixx would not become materially misleading unless the corporation was aware of a “statistically significant” number of adverse events threatening Zicam’s commercial viability.²⁰ The district court also determined that the plaintiff failed to show scienter that Matrixx disbelieved their public statements regarding Zicam product safety.²¹

On appeal, the Ninth Circuit reviewed the case *de novo*, considering whether the district court erred in granting Matrixx’s 12(b)(6) motion to dismiss.²² The Ninth

had been sued in at least three cases on anosmia claims. *Id.* Following the *Dow Jones* article on January 30, 2004, MTXX fell from \$13.55 to \$11.97 per share and after the *GMA* report on February 6, 2004, the price fell from \$13.05 to \$9.94 per share, its largest ever one-day drop in heavy trading. *Id.* After Matrixx’s denial of the *Dow Jones* report, MTXX rebounded to \$13.40 per share on February 3, 2004. *Id.* at 1174.

16. *Id.* at 1173. Matrixx asserted in press releases that “[i]n no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function” and calling the allegations “completely unfounded and misleading.” *Id.* at 1173. Matrixx also stated that the zinc sulfate used in the 1930s polio studies linking zinc to anosmia is an entirely different compound from the zinc gluconate used in Zicam products. *Id.* at 1174.

17. *Id.* at 1174. Matrixx reported in the 8-K filing that a panel of physicians and scientists had convened to review the scientific data and concluded that there was “insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person’s ability to smell.” *Id.*

18. The plaintiffs claimed that the corporation’s omission of a material fact (the possible link between Zicam intranasal application and anosmia), material misstatements regarding product safety, and failure to alert shareholders of four pending products liability lawsuits gave rise to a duty to disclose and correct prior statements. *Siracusano*, 2005 WL 3970117 at *1. A total of nine plaintiffs were involved in the four lawsuits at the end of the class period. *Siracusano*, 585 F.3d at 1170–71. *See also infra* Part III (discussing Rule 10b-5).

19. *Siracusano*, 2005 WL 3970117 at *5–9.

20. *Id.* at *6–7. The district court analogized the facts to *In re Carter-Wallace Sec. Litig. v. Hoyt*. *Id.* at 6. As there was no consensus between adverse medical reports and clinical data, the district court held that Matrixx did not make a material statement or omission of fact. *Id.* at *7. The court stated that once a consensus emerges between clinical data and adverse event reports, then the information is “sufficiently serious and frequent to affect future earnings.” *Id.* The district court held that clinical trials by Matrixx did not disclose any risk of anosmia and were at odds with the adverse event reports; therefore, there was no medical consensus. *Id.* at *7.

21. *Id.* at *8.

22. *Siracusano*, 585 F.3d at 1170.

Circuit rejected the “statistical significance” test adopted by the lower court, reasoning that the bright-line rule was inappropriate to “delicate assessments of the inferences a ‘reasonable shareholder’ would draw from a given set of facts and the significance of those inferences to him.”²³ Instead, the Ninth Circuit engaged in a fact-specific inquiry to decide whether a reasonable investor would have deemed the data material to her informed decision-making.²⁴

The Ninth Circuit determined that the allegations were pled with specificity and taken together would have been material to a reasonable investor under all of the circumstances.²⁵ The court considered the reports to Matrixx by medical researchers and specialists regarding their professional concerns about the levels of zinc in the intranasal applications of Zicam, the four lawsuits in four states involving nine plaintiffs during the class period, and more than 165 cases identified by April 2004 to have a “substantial likelihood” of altering the reasonable investors determination of the “total mix” of information about Matrixx.²⁶ The Ninth Circuit held that twelve adverse event reports of anosmia, together with four impending product liability suits, were material and gave rise to a duty to disclose.²⁷ With respect to scienter, the Ninth Circuit found that the inference of scienter was “cogent and at least as compelling” as the alternative.²⁸ The Ninth Circuit reversed the district court’s ruling that the plaintiff had not sufficiently pled materiality and scienter and remanded the case.²⁹

The United States Supreme Court granted certiorari to resolve a circuit split and determine whether “statistical significance” is required to plead materiality in a securities fraud claim.³⁰

23. *Id.* at 1178–79 (noting that “statistical significance” cannot be determined as a matter of law precisely because “statistical significance is a question of fact”) (citing *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621 (S.D.N.Y. 2008)).

24. *Id.* at 1179.

25. *Id.* at 1183.

26. *Id.* at 1179. The Ninth Circuit deemed the following reports supported a prima facie showing of materiality: (1) Dr. Hirsch’s and Dr. Linschoten’s reports to Matrixx of one patient each with anosmia; (2) A conversation between Linschoten and a Matrixx VP regarding studies that linked anosmia and zinc sulfate; (3) Linschoten’s e-mail to Matrixx with abstracts linking zinc sulfate and loss of smell on September 20, 2002; (4) University of Colorado researcher Jafek’s presentation of ten or eleven cases of patients with loss of smell after using Zicam; (5) four lawsuits filed in four states involving nine users of Zicam who experienced anosmia; (6) the 165 cases reported by April 2004 (these cases were stricken from the record by the district court as they were reported after the close of the class period). *Id.*

27. *Id.* at 1179–80.

28. *Id.* at 1183. Between 1999 and 2003, Matrixx knew of a suspected link between zinc gluconate and anosmia based on adverse event reports from medical experts and researchers. *Id.* at 1182. Despite these reports, the Ninth Circuit found that Matrixx asserted the safety of Zicam in several press releases without conclusive studies on the matter and did not disclose pending lawsuits in a November 2003 filing to the SEC. *Id.* at 1182–83. Although scienter is often proven by a personal financial motivation absent in this case, the absence of such proof is not fatal. *Id.* at 1182.

29. *Id.* at 1183.

30. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1313 (2011).

II. LEGAL BACKGROUND

Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 are designed to regulate and prevent unfair and manipulative practices in the securities markets.³¹ Section 10(b) makes it illegal for “any person, directly or indirectly . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement . . . any manipulative or deceptive device”³² Rule 10b-5 proscribes manipulative and deceptive practices, stating that it is “unlawful for any person, directly or indirectly . . . 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”³³

To survive a motion to dismiss in a securities fraud claim brought under Section 10(b) and Rule 10b-5, the plaintiff must make a prima facie showing of six elements: “(1) the misrepresentation or omission of a material fact; (2) made with scienter; (3) in connection with the purchase or sale of a security; (4) on which the plaintiff relied; and (5) that was causally connected to (6) the plaintiff’s loss.”³⁴ The threshold element in any securities fraud case is materiality, and since *Basic Inc. v. Levinson*,³⁵ courts have sought to strike a balance that will lead to disclosure of material information without flooding the market with inconsequential data.³⁶ The *Basic* Court outlined two tests for materiality—one for events certain to occur and the other for contingent events—leading to a circuit split.³⁷

31. See Message from the President of the United States, March 29, 1933, *reprinted in* H.R. Rep. No. 73-12 (1933), *reprinted in* 2 J. S. Ellenberger and Ellen P. Mahar, *Legislative History of the Securities Act of 1933 and Securities Exchange Act of 1934*, Item 15 (1973) (calling for “full publicity and information, and . . . [proposing that] no essentially important element attending the issue shall be concealed from the buying public” in order to promote public confidence in the securities market); S. Rep. No. 73-47, at 1 *reprinted in* 2 J. S. Ellenberger and Ellen P. Mahar, *Legislative History of the Securities Act of 1933 and Securities Exchange Act of 1934*, Item 17 (1973) (stating the purpose of Securities Act is to “inform[] the investor of the facts concerning securities to be offered for sale in interstate and foreign commerce and provid[e] protection against fraud and misrepresentation”); and *Basic Inc. v. Levinson*, 485 U.S. 224, 230 (1988) (noting the purpose of the Securities Exchange Act was “to protect investors against manipulation of stock prices”).

32. 15 U.S.C. § 78j (2006).

33. 17 C.F.R. § 240.10b-5 (2010).

34. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005).

35. 485 U.S. 224 (1988).

36. *TSC Indus., Inc. v. Northway*, 426 U.S. 438 (1976).

37. The two tests courts should use to determine materiality of a misstatement of fact or omission are the *TSC Indus. Inc. v. Northway, Inc.* standard (“total mix”), when the impact of an event is certain; and the *SEC v. Tex. Gulf Sulphur Co.* test (“probability/magnitude”), when an event is contingent or speculative. *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988). The First, Second and Third Circuits applied the “probability/magnitude” test, measuring the magnitude of an event by “statistical significance,” while the Ninth Circuit used the “total mix” standard. *Compare* *In re Carter–Wallace*, 150 F.3d 153, 157 (2d Cir. 1998) (applying a test of statistical significance for materiality), *Oran v. Stafford*, 226 F.3d 275, 283–84 (3d Cir. 2000) (Alito, J.) (finding that absent a showing of “statistical significance” that proved causation, non disclosure was not material), and *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008) (stating that as a matter of law, adverse event reports must be statistically significant) *with* *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1179 (9th Cir. 2009) (holding that materiality turns on the “total mix” standard articulated in *Basic v. Levinson*).

The Court held in *Ernst & Ernst v. Hochfelder*³⁸ that scienter, the second element, is required in a securities fraud claim.³⁹ After the passage of Private Securities Litigation Reform Act of 1995,⁴⁰ the Court held in *Tellabs v. Makor*⁴¹ that a “‘strong inference’ of scienter” requires the “‘intent to deceive, manipulate or defraud” to be at least as cogent as any other presumption.⁴²

A. *Basic Develops the Fundamentals of Materiality.*

Interpreting Rule 10b-5,⁴³ the United States Supreme Court articulated a legal standard for materiality that aimed to balance the goal of corporate transparency with the risk of a marketplace flooded with useless information.⁴⁴ In *Basic Inc. v. Levinson*,⁴⁵ a securities fraud claim concerning non-disclosure of pre-merger discussions, the Court articulated two tests for materiality, expressly adopting the holding in *SEC v. Tex. Gulf Sulphur*⁴⁶ in the 10(b) context for contingent events and discussing the *TSC Indus., Inc. v. Northway, Inc.*⁴⁷ rule when events are certain.⁴⁸ The *Basic* Court stated that when the impact of an event is certain, courts should

38. 425 U.S. 185 (1976).

39. *Id.* at 197–99 (construing the language of § 10-b “to use or employ . . . any manipulative or deceptive device or contrivance” as reflecting Congressional intent for a statement or omission to have been made with scienter, an intent to manipulate and noting that manipulation is a term of art in the securities markets wherein the price of securities are artificially affected and controlled in order to cheat or mislead investors).

40. 15 U.S.C. § 78u-4(b)(1), (2) (2006). PSLRA was enacted with the dual goals of creating a uniform pleading standard that would curb some abuses of § 10(b) private actions and preserving an investor’s ability to recover. *Tellabs v. Makor*, 551 U.S. 308, 322 (2007).

41. 551 U.S. 308 (2007). In *Tellabs*, the Court held that the inference of scienter is a comparative analysis between the culpable and “plausible, nonculpable explanations.” *Id.* at 323–24.

42. *Id.* at 324. The SEC addressed scienter in SAB 99, stating that in certain circumstances an intentional immaterial misstatement or omission of fact may be unlawful. SEC Staff Accounting Bulletin No. 99, 64 Fed. Reg. 45150 (Aug. 12, 1999) (“SAB 99”). During oral arguments in this case, Justice Kennedy questioned whether the independent analysis is correct and whether the two elements should be analyzed concurrently. Transcript of Oral Argument at 31, *Matrixx Initiatives, Inc. v. Siracusano*, 130 S. Ct. 3411 (2011) (No. 09–1156).

43. 17 C.F.R. 240.10b–5 (2010).

44. See *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448–49 (1976) (articulating the vital balance between transparency in the marketplace and the potential adverse consequences of disclosure that would “bury the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking”).

45. *Basic Inc. v. Levinson*, 485 U.S. 224, 226 (1988) (noting that shareholders who sold stock prior to a formal merger announcement alleged material misrepresentation of facts in violation of §10(b) and Rule 10b-5 because *Basic* publicly denied merger discussions).

46. *SEC v. Tex. Gulf Sulphur*, 401 F.2d 833 (2d Cir. 1968). In *Tex. Gulf Sulphur*, corporate insiders traded on the undisclosed information, and the company put out an ambiguous statement about the drilling results prior to full disclosure contrary to the report and indicia that this was one of the biggest finds in recent memory. *Id.* at 849–51. The *Tex. Gulf Sulphur* court decided that nonpublic information about vast ore deposits located close to the surface was material by examining the importance attached to the information by the corporation and corporate insiders as well as the market response to the magnitude of the discovery after disclosure. *Id.*

47. 426 U.S. 438 (1976).

48. *TSC Indus., Inc.* 426 U.S. at 449–50 (holding that materiality is a mixed question of law and fact, and only where the omissions were “so obviously important to an investor, that reasonable minds cannot differ on the question of materiality” is the question properly settled as a matter of law by summary judgment).

measure materiality by the “substantial likelihood” that the event will significantly alter the “total mix” a reasonable investor deems important to investment decisions.⁴⁹ Alternatively, in cases of contingent or speculative events, courts should determine materiality by balancing the “probability the event will occur relative to the anticipated magnitude of the event” compared with total company activity.⁵⁰

Basic was remanded and the lower court was advised to apply the “probability/magnitude” test to non-disclosure of pre-merger discussions and weigh probabilistic factors such as “board resolutions, instructions to investment bankers, and actual negotiations” against “the magnitude of the transaction to the issuer of the securities[,] . . . the size of the two corporate entities[,] and the potential premiums over market value.”⁵¹ The *Basic* Court rejected the “agreement-in-principle” rule for materiality in the merger context, noting that materiality is an inherently fact-specific inquiry and any bright-line rule in which any one fact is considered dispositive is necessarily “overinclusive or underinclusive.”⁵²

B. Applying Basic Is Fundamentally Complex.

After *Basic*, the First, Second and Third Circuits looked to a quantitative measurement of “probability/magnitude” in the pharmaceutical context and adopted a five-percent quantitative “statistical significance” valuation while the Ninth Circuit applied the “total mix” rule.⁵³ For example, in *In re Carter-Wallace*,⁵⁴ the Second Circuit held that a pharmaceutical company had no duty to disclose information regarding adverse events suffered by users until there was “statistically significant evidence” of a causal link from the drug to the side effect.⁵⁵ The *In re Carter-Wallace* case involved deaths related to the use of the drug Felbatol, the first of which was reported in January 1994.⁵⁶ Carter-Wallace did not disclose this information until August 1994 when there was evidence of ten deaths, causing a

49. *Basic*, 485 U.S. at 231–32.

50. *Id.* (applying the probability/magnitude rule in the pre-merger context) (internal citations omitted).

51. *Id.* at 239, 250 (indicating this was a non-exhaustive list of considerations).

52. *Id.* at 236 (determining that as materiality is “an inherently fact-specific finding” that precludes “any approach that designates a single fact or occurrence as always determinative”).

53. See *supra* note 37 and accompanying text. Notably, the SEC released SAB 99 out of concern for exclusive reliance on “statistical significance” in financial statement reporting. SEC Staff Accounting Bulletin No. 99, 64 Fed. Reg. 45150 (Aug. 12, 1999). SAB 99 states that “statistical significance” is not dispositive to determine materiality and notes other qualitative considerations such as: (1) “masks a change in earnings or other trends”; (2) “hides a failure to meet analysts’ consensus expectations for the enterprise”; (3) concerns a business segment that plays “a significant role in the registrant’s operations or profitability”; and (4) concerns certain types of disclosures that have historically “demonstrated volatility of the price of a registrant’s securities” thereby showing whether shareholders regard “quantitatively small misstatements as material.” *Id.*

54. 150 F.3d 153 (2d Cir. 1998).

55. *Id.* at 157 (holding that a pharmaceutical company’s duty to disclose adverse event reports arise not from “isolated reports of illnesses,” but only when “those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings”).

56. *Id.* at 155.

decline in stock price.⁵⁷ Stockholders alleged that Carter-Wallace’s failure to disclose the deaths constituted material misstatements in the 1994 10-K “Report to Shareholders.”⁵⁸ The *In re Carter-Wallace* court affirmed that failing to disclose reports of Felbatol-related aplastic anemia deaths was not material, because Carter-Wallace “justifiably worked with” the Food and Drug Administration (“FDA”) to ascertain the probability of a link and had no duty to disclose until they had reason to believe Felbatol’s “commercial viability was threatened.”⁵⁹

The First and Third Circuits also adopted the “statistical significance” rule in cases where pharmaceutical companies disclosed serious potential side effects to FDA-approved drugs some time after the first report of a serious side effect.⁶⁰ Citing *In re Carter-Wallace*, the Third Circuit ruled in *Oran v. Stafford*⁶¹ that a failure to disclose a potential link between use of a weight loss drug known as fen-phen and a rare heart valve disorder was not material until the adverse event reports provided “statistically significant” evidence of causation that would impact future earnings.⁶² As in *In re Carter-Wallace*, the drug company in *Oran* received reports of a serious side effect and disclosed the information only after tracking twenty-four cases of a rare heart valve disorder with the Mayo Clinic.⁶³ In *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*,⁶⁴ Biogen pulled its drug TYSABRI from the market ten days after learning about a potential infectious link and one death.⁶⁵ The First Circuit assumed *arguendo* that the materiality element was met, but noted that, as a matter of law, adverse event reports must be “statistically significant” in order to satisfy the materiality element of a securities fraud claim.⁶⁶ Thus, the First, Second and Third Circuits applied a quantitative measure of “statistical significance” to determine materiality.

In contrast, the Ninth Circuit held that the district court erred when it applied the “statistical significance” test to materiality in *Siracusano v. Matrixx Initiatives, Inc.*,⁶⁷ and instead applied the “total mix” standard.⁶⁸ Rejecting a “statistical

57. *Id.* Carter–Wallace issued a “Dear Doctor” letter in coordination with the FDA and recommended that doctors stop prescribing the drug in most patients because of evidence of a fatal form of bone marrow failure. *Id.*

58. *Id.* at 157.

59. *Id.*

60. See *supra* note 37 and accompanying text.

61. *Oran v. Stafford*, 226 F.3d 275 (2000).

62. *Id.* at 283. In *Oran*, American Home Products was alerted to a potential link in Europe as early as 1994, but disclosed the information only after monitoring and confirming twenty-four cases at the Mayo Clinic from March to July 1997. *Id.* Unlike *In re Carter–Wallace*, the disclosure elicited no market change at the time of disclosure. *Id.*

63. *Oran*, 226 F.3d at 282–83 (applying the efficient market hypothesis rule in addition to the “statistical significance” test, then–Judge Alito held that because the stock price remained constant after disclosure, the information was not material as a matter of law) (citing *Burlington*, 114 F.3d at 1425).

64. 537 F.3d 35 (1st Cir. 2008).

65. *Id.* at 37. FDA approval of Biogen’s drug TYSABRI was fast-tracked for use by multiple sclerosis and Crohn’s disease patients; five out of 3,900 patients in a clinical trial suffered an infection, one died. *Id.* at 37, 40.

66. *Id.* at 49–50 (affirming that the plaintiff had not sufficiently pled scienter).

67. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009), *aff’d*, 131 S. Ct. 1309 (2011).

significance” test, the Ninth Circuit reasoned that the United States Supreme Court had abandoned a bright-line rule in favor of a fact-specific inquiry of information a reasonable investor would find significant to her investment decisions.⁶⁹

III. THE SUPREME COURT’S REASONING

The United States Supreme Court affirmed the Ninth Circuit’s decision in a unanimous opinion, holding that the Respondents stated a claim under Section 10(b) and Rule 10b-5.⁷⁰ The Court reaffirmed *Basic*,⁷¹ stating the question of materiality turns on “whether a *reasonable* investor would have viewed the nondisclosed information as having *significantly* altered the ‘total mix’ of information made available.”⁷² The Court rejected any single factor as determinative of materiality as “necessarily . . . overinclusive or underinclusive.”⁷³ In so ruling, the Court looked to *Basic* when stating that a test of statistical significance for materiality would “artificially exclude[e]” relevant information that a reasonable investor would incorporate into trading decisions.⁷⁴ In addition, the Court stated that while adverse events alone are insufficient to plead materiality, “statistical significance” of adverse event reports is neither irrelevant nor dispositive.⁷⁵ “Something more” than adverse events is required, such as “the source, content, and context of the reports.”⁷⁶ Finally, the Court re-affirmed that there is no affirmative duty to disclose material information under Section 10(b) and Rule 10b-5, rather the duty arises to clarify or correct potentially misleading statements.⁷⁷

68. *Id.* at 1178.

69. *Id.* at 1178–81 (applying the *Basic* Court’s “total mix” standard of materiality).

70. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1314 (2011). The case was noted as an unusual victory for plaintiffs in securities fraud cases. Robert Barnes, *Pair of Supreme Court Rulings Make It Easier to Sue Companies*, WASH. POST, March 23, 2011, at A15, available at http://www.washingtonpost.com/politics/supreme-court-sides-with-investors-workers-in-two-business-related-cases/2011/03/22/ABbxzBDB_story.html; and Nathan Koppel, *Securities-Fraud Plaintiffs Get Rare Win at Supreme Court*, WALL ST. J. LAW BLOG (March 22, 2011, 1:38 PM), <http://blogs.wsj.com/law/2011/03/22/securities-fraud-plaintiffs-get-rare-win-at-supreme-court/?KEYWORDS=%22Securities-Fraud+Plaintiffs+Get+Rare+Win+at+Supreme+Court%22>.

71. 485 U.S. 224 (1988).

72. *Matrixx*, 131 S. Ct. at 1321–22 (citing to *Basic*, 485 U.S. at 232) (internal quotation omitted).

73. *Id.* at 1318.

74. *Id.* at 1319–20. Critics note that the decision leaves companies without a critical benchmark to determine whether or not to disclose adverse events. Carl Bialik, *Making a Stat Less Significant*, WALL ST. J., April 2, 2011, available at <http://online.wsj.com/article/SB10001424052748703712504576235683249040812.html?KEYWORDS=%22making+a+stat+less+significant%22>.

75. *Matrixx*, 131 S. Ct. at 1321.

76. *Id.* The Court also noted a multi-factor test that medical researchers and the FDA rely on when assessing causation of adverse events as “strength of the association,” “temporal relationship of product use and the event,” “consistency of findings across available data sources,” “evidence of a dose-response for the effect,” “biological plausibility,” “seriousness of the event relative to the disease being treated,” “potential to mitigate the risk in the population,” “feasibility of further study using observational or controlled clinical study designs,” and “degree of benefit the product provides, including availability of other therapies.” *Id.* at 1320 (internal citations omitted). The Court noted that the FDA requires warning labels once there is a suspicion of causation, not proof of actual causation to the adverse event. *Id.* (internal citations omitted).

77. *Id.* at 1321–22.

Applying the *Basic* “total mix” standard here, the Court determined that the Respondents met the threshold for materiality.⁷⁸ Looking to the “source, content, and context” of the anosmia reports, the Court pointed out that the three medical professionals and researchers raised plausible questions of biological causation between intranasal application of zinc gluconate and anosmia, sharing with Matrixx evidence from prior studies demonstrating the biological link.⁷⁹ Furthermore, the Court noted that consumers, weighing the risk of anosmia against the benefit of using Zicam, would have used substitutes.⁸⁰ Given the importance of the Zicam family of products to the corporation, the undisclosed information constituted material facts.⁸¹

With respect to the element of scienter, the Court stated that a plaintiff must plead “with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind” and sufficiently to allege that “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.”⁸² The Court found that an inference of deliberate recklessness by Matrixx to protect their market share was at least as compelling as the argument that Matrixx believed the product was safe, but noted proving such facts at trial and “establish[ing] scienter is an altogether different question.”⁸³

The Court held that the Respondents adequately stated a claim under Section 10(b) and Rule 10b-5.⁸⁴

IV. ANALYSIS

The United States Supreme Court correctly decided in *Matrixx Initiatives, Inc. v. Siracusano* that the Respondents sufficiently pled materiality and scienter because Matrixx failed to correct public statements denying allegations of a link between anosmia and the company’s leading revenue-generating product, absent independent basis for the denials.⁸⁵ Rejecting a “statistical significance” standard and determining that adverse event reports alone are insufficient to plead materiality in a securities fraud action, the Court stopped short of clarifying how

78. *Id.* at 1323.

79. *Id.* at 1322. The Court observed that Matrixx dismissed the warnings from medical researchers as unfounded, without having conducted their own animal or human research. *Id.*

80. *Id.* at 1323.

81. *Id.*

82. *Id.* at 1324–25 (internal citations omitted). The court held the respondents sufficiently pled scienter, noting that the evaluation of allegations must be viewed “holistically.” *Id.*

83. *Id.* at 1325. The court pointed to the following facts: Zicam comprised seventy percent of Matrixx’s sales; Matrixx announced fifty to eighty percent rise in sales on the strength of Zicam; Matrixx dismissed credible reports from medical researchers and prevented Dr. Jafek from using Zicam name in a national presentation; and after news stories reported a possible link, Matrixx called the reports unfounded without conducting their own studies. *Id.*

84. *Id.* at 1313–14.

85. *See infra* Part I.

corporations and courts should apply the “something more” standard.⁸⁶ Given the numerous “sources, content, and context[s]” for adverse event reports, the Court’s decision creates confusion for corporations seeking to understand when a prior statement may trigger a duty to correct a false or misleading material statement, and also creates challenges for courts that must apply a complex standard to similarly-situated companies.⁸⁷ Unsure of their potential exposure under a “something more” standard, companies may unnecessarily disclose information and thereby provide less clarity to shareholders trying to make informed investment decisions.⁸⁸

A. Something More Is Needed Than a “Something More” Standard.

The *Matrixx* Court determined that, in the absence of statistical significance, “the source, content, and context of the reports” can support an allegation that a reasonable investor would deem the reports significant to her investment decisions.⁸⁹ Here, the Court pointed to the fact that two medical researchers informed *Matrixx* about clinical studies on the effect of the intranasal application of a different zinc compound on loss of smell as critical data to their materiality determination.⁹⁰

The “something more” rule adds another element of ambiguity to an already nebulous materiality definition.⁹¹ Prior to *Matrixx*, scholars and practitioners described the case law defining materiality as “elusive” and “ever changing,” and commented that the determination of materiality is often solely ascertainable post hoc.⁹² After *Matrixx*, this assessment has not changed. A recent article quoted practitioners stating that the application of materiality is “very difficult” and “one of the most difficult determinations. And it’s going to remain[] that way. I think

86. *Matrixx*, 131 S. Ct. at 1321, 1323 (finding that the Respondents alleged facts that “revealed a plausible causal relationship” sufficient to plead materiality). The case mentions the pleading standard under *Twombly* and *Iqbal*, but critics have noted that the Court relied primarily on the pre-PLSRA cases of *Basic* and *TSC*. See e.g. Allan Horwich, *An Inquiry into the Perception of Materiality as an Element of Scienter under SEC Rule 10b-5*, 67 BUS. LAW. 1 n. 63 (2011).

87. See e.g. *Matrixx*, 131 S. Ct. at 1321 (listing several forms of adverse event reports).

88. See Brief for the Pharm. Research and Mfr. of Am. and the Biotechnology Indus. Org. as Amicus Curiae Supporting Petitioners at 24–27 *Matrixx v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09–1156), 2010 WL 3426276 at *24–27 [hereinafter Pharm. Research Brief] (noting that absent a clear standard, companies will disclose too much to shareholders to the detriment of shareholders’ decision-making process); and Tod Reichert, *Matrixx Initiatives, Inc. v. Siracusano: A Lowering of the Materiality Bar?*, CORPORATE COMPLIANCE INSIGHTS, November 1, 2010, <http://www.corporatecomplianceinsights.com/matrixx-initiatives-inc-v-siracusano-a-lowering-of-the-materiality-bar/> (cautioning that a threshold lower than statistical significance may cause a change in the frequency of corporate disclosures).

89. *Matrixx*, 131 S. Ct. at 1321–22.

90. *Id.* at 1322. Dr. Linschoten forwarded to a *Matrixx* Vice President “abstracts on the link between zinc sulfate and the loss of smell” conducted in the 1930s with polio patients. *Siracusano v. Matrixx*, 585 F.3d 1167, 1170 (2009).

91. Yvonne Ching Ling Lee, *The Elusive Concept of “Materiality” Under U.S. Federal Securities Laws*, 40 WILLAMETTE L. REV. 661, 663–64 (2004) (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)).

92. *Id.* at 663–64 (calling materiality a “gotcha’ standard” because courts look to share price fluctuations and SEC enforcement actions); and Marc I. Steinberg & Jason B. Meyers, *Lurking in the Shadows: The Hidden Issues of the Securities and Exchange Commission’s Regulation FD*, 27 J. CORP. L. 173, 188 (2002).

the Supreme Court decision [in *Matrixx*] is saying, ‘Go out there and struggle, and best of luck for the next few years.’”⁹³

Under the new “something more” standard, companies must try to ascertain materiality by assessing the relative significance of diverse sources, content, and context of potentially conflicting data or conflicting interpretations of data.⁹⁴ The FDA has regulatory authority to approve and monitor prescription drugs and over-the-counter drugs sold in the United States, and the agency strictly regulates the reporting requirements of adverse reactions to drugs throughout the application and post-marketing processes.⁹⁵ The FDA’s mandatory regulation of drug safety reporting requires the several industry sources—applicants, manufacturers, packers, or distributors—report each serious or unexpected adverse drug experience within fifteen calendar days after receiving the report and to investigate and follow up with the FDA after new information is available or upon request by the FDA.⁹⁶ While the regulations note that the report does not evidence conclusions by the reporting entity that the drug caused the reaction, the FDA has prophylactic power to withdraw the drug from the market absent proof of causation.⁹⁷

In addition to these mandatory reporting sources, the FDA’s MedWatch program has been rolled out to the general public, and health professionals and consumers may voluntarily file an adverse event report online.⁹⁸ MedWatch partners include over one-hundred organizations such as the American Medical

93. Horwich, *supra* note 86, at n. 81 (2011) (citing Materiality: The Hardest Determination 1, 5, 10 (Oct. 5, 2011) (transcript available at http://www.thecorporatecounsel.net/member/Webcast/2011/10_05/transcript.htm) (password required)). Analyzing the outcome immediately following the *Matrixx* decision, several law firm articles keyed on the Court’s statement that companies can control the information they have a duty to disclose under securities laws by “controlling what they say to the market.” See Gay Parks Rainville & Deirdre E. McInerney, *Matrixx Initiatives, Inc. v. Siracusano: Supreme Court Snuffs Out ‘Statistical Significance’ Test for Pleading Rule 10b-5 Claims Against Pharmaceutical Companies*, PEPPER HAMILTON LLP CLIENT ALERT, March 24, 2011 (advising life sciences companies to “exercise . . . control” over disclosure); and *Decision in Matrixx Initiatives, Inc. v. Siracusano Rejects Bright-Line Rule in Securities Fraud Action Based on Pharmaceutical Company’s Failure to Disclose Adverse Event*, DAVIS POLK CLIENT NEWSFLASH, March 22, 2011, available at http://www.davispolk.com/files/Publication/3d1e80e4-07c6-4f1f-923d-00d269490fbe/Presentation/PublicationAttachment/3e8639cf-da6f-4b7d-abf4-01e02f9cae13/03.22.11_lit.html (last visited April 22, 2012) (noting that all adverse event reports need not be disclosed).

94. William O. Fisher, *Key Disclosure Issues for Life Sciences Companies: FDA Product Approval, Clinical Test Results, and Government Inspections*, 8 MICH. TELECOMM. & TECH L.REV. 115, 143–44 (2002) (stating that two researchers, even within the same company, may interpret the same data differently).

95. 21 U.S.C. § 355 *et seq.* (2006); 21 C.F.R. § 310.305 (2010); 21 C.F.R. § 312.32 (2010); and 21 C.F.R. § 314.80 (2010).

96. Serious adverse drug experiences are defined as those resulting in “[d]eath, 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,” while unexpected adverse drug experiences include “[a]ny adverse drug experience that is not listed in the current labeling for the drug product.” 21 C.F.R. §§ 310.305(b), 314.80(a). The information reported is made publicly available through the FDA’s online Adverse Event Report System (AERS). http://www.fda.gov/Drugs/InformationOnDrugs/ucm135151.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=AERS&utm_content=1.

97. 21 C.F.R. §§ 310.305(g), 314.80(k). See also *Matrixx v. Siracusano*, 131 S. Ct. 1309, 1320 (2011).

98. *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/MedWatch/default.htm> (last visited April 22, 2012) (using online FDA Form 3500A).

Association, CVS Pharmacy, BlueCross Blue Shield Association, and PDR Network, LLC.⁹⁹ The FDA launched a Transparency Initiative in 2009, creating a Task Force to educate and solicit additional feedback from consumers, health professionals, medical researchers, and industry on an ongoing basis.¹⁰⁰ Companies also receive adverse event reports directly from consumers, medical professionals, and the FDA.¹⁰¹ The array of sources for adverse event reports is, therefore, considerable, while the accuracy and completeness of adverse event reports can vary widely.¹⁰²

Beyond the source, companies and courts must also consider the content and context of adverse event reports.¹⁰³ Companies and the FDA receive adverse event reports in different forms, ranging from direct complaints to doctor reports and from medical journal articles to published clinical studies.¹⁰⁴ One scholar states that adverse event reports “rarely, if ever” provide the “good experimental or observational” data required to make reliable inferences of causation.¹⁰⁵ Adverse event reports, therefore, often trigger companies to conduct additional studies for reliable data, and these studies may take the form of a controlled study or an observational study.¹⁰⁶ A controlled study, on the one hand, may demonstrate a degree of confidence regarding causation, while an observational study may indicate an association between drug use and an adverse reaction.¹⁰⁷ Some studies are peer-reviewed, indicating a greater degree of confidence in the data’s credibility and interpretation, while others are not.¹⁰⁸

99. For a complete listing of MedWatch partners, including medical professional associations, insurance companies and drugstores see *MedWatch Partners*, FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/MedWatch/ucm170520.htm> (last visited April 22, 2012).

100. James E. Valentine, *FDA Transparency Initiative (March 2010)*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForHealthProfessionals/ArticlesofInterest/ucm206849.htm> (last visited April 22, 2012). The FDA publicly posts both mandatory and voluntary adverse event reports on their website for investor and consumer review which in 2010 numbered 758,890. *Reports Received and Reports Entered into AERS by Year*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm>. The Matrixx Court seemingly disregarded the argument that because mandatory and voluntary reporting information is publicly available, the data was reflected in the share price and available to investors’ consideration. Pharm. Research Brief, *supra* note 88 at 16 (citing *Basic v. Levinson*, 485 U.S. 224, 246 (1988)).

101. *See generally* Brief of BayBio as Amicus Curiae Supporting Petitioners at 8 *Matrixx Industries v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426273 at *8 [hereinafter *BayBio Brief*] (noting that life sciences companies are inundated with adverse event report information).

102. *Id.* at *9 (stating that adverse event report data is often acquired “haphazardly or selectively”) (citing David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, in *Reference Manual on Scientific Evidence* 83, 91 (Federal Judicial Center, 2d ed. 2000)).

103. *See infra* Part III.

104. *Matrixx Indus., Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011).

105. Kaye, *supra* note 4, at 5.

106. *BayBio Brief*, *supra* note 101, at 10–14. Here, the abstract provided to Matrixx indicated a link between anosmia and intranasal application of zinc sulfate, which ultimately “incentivized” Matrixx to engage in further studies on the impact of zinc gluconate as the active ingredient. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1183 (9th Cir. 2009), *aff’d*.

107. *Id.* at *11–14.

108. The FDA website lists peer review plans and peer review results for various studies. *Peer Review of Scientific Information and Assessments*, FOOD & DRUG ADMIN., <http://www.fda.gov/ScienceResearch/>

The Court might have clarified the decision by indicating a minimum threshold of clinical or observational study that would satisfy the standard and thereby indicate a “plausible causal relationship.”¹⁰⁹ Instead, corporations and courts are left to “go out there and struggle” to determine the definition of materiality.¹¹⁰

Given the many potential combinations of source, content, and context of adverse event reports, the Court’s lack of guidance on how to apply “something more” creates confusion for corporations and courts alike.

B. Lower Courts Applying the Matrixx Pleading Standard Provide Mixed Signals.

After the *Matrixx* decision, pharmaceutical companies are faced with an even greater challenge to determine whether a duty to disclose has been triggered based on prior public statements. A pharmaceutical company faced with determining whether the source, content, and context of an adverse event report is material or merely suggests cause for further inquiry may look to post-*Matrixx* decisions for guidance.¹¹¹ The lower court interpretations of *Matrixx* provide limited guidance at best.¹¹²

Recent court decisions reflect the ongoing challenge of balancing material disclosure against protecting the market from an influx of trivial information.¹¹³ Some courts interpreting *Matrixx* appear cautious about setting too low a standard for materiality or, alternatively, indicate an uncertainty about the implications of *Matrixx*. For example, the First Circuit has affirmed the dismissal of two securities fraud claims in which the shareholders deemed disclosures incomplete and, therefore, misleading.¹¹⁴ The First Circuit noted that “[w]hile a statement of risk ‘does not insulate the speaker from liability . . . neither does it create liability simply because it does not disclose, at the level of detail the plaintiffs request in retrospect, all of the factors that contribute to the risk assessment.’”¹¹⁵ The Eighth Circuit recently affirmed dismissal of a case in which the plaintiff alleged a company’s prior

SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=peer+review&utm_content=1.

109. See *infra* note 86. The Court might also have provided examples as to how corporations and courts should evaluate the various sources of adverse event reports or, at a minimum, how to consider reports that originate along the spectrum (from consumers to pharmacists and from doctors to medical researchers and the FDA).

110. See *infra* note 93 and accompanying text.

111. See generally Edward W. Little Jr. & Kelly A. Gabos, *Matrixx and Recent Lower Court Decisions*, 22 ABA SECURITIES LITIGATION COMMITTEE 20, 22–23 (2012) (analyzing recent securities litigation decisions post-*Matrixx*).

112. See generally *id.*

113. See *infra* note 36 and accompanying text.

114. Little & Gabos, *supra* note 111, at 22–23 (citing *Mississippi Pub. Emp. Ret. Sys.*, 649 F.3d 5 (1st Cir. 2011) and *Hill v. Gozani*, 651 F.3d 151 (1st Cir. 2011)).

115. *Mississippi Pub. Emp. Ret. Sys.*, 649 F.3d at 29 (citing *Hill v. Gozani*, 683 F.3d 40, 60 (1st Cir. 2010), *aff’d*, 651 F.3d 151 (1st Cir. 2011)).

class period disclosures established a duty to make future disclosures.¹¹⁶ Notably, the court left open the possibility that the *Matrixx* decision may imply that a company's pattern of disclosure may establish a duty to disclose, but indicated that such facts were not present in the instant case.¹¹⁷ In contrast, other courts have determined that a plaintiff had sufficiently pled materiality and scienter under the *Matrixx* pleading standard and a duty to disclose was triggered by overly optimistic or incomplete prior material statements.¹¹⁸ In *Local 731 I.B. of T. Excavators and Pavers Pension Trust Fund v. Swanson*,¹¹⁹ the U.S. District Court of Delaware determined that the company's statements were distinguishable from mere "puffery" and constituted statements of opinion resting on a factual basis that required correction.¹²⁰ In a case outside the pharmaceutical context, the court in *City of Ann Arbor Employees' Retirement System v. Sonoco Products Co.*¹²¹ denied summary judgment in which the plaintiff alleged that the corporation failed to disclose price concessions when it shared price increases in order to allegedly project a position of market strength.¹²²

Corporations continue to lack clarity from both the *Matrixx* Court and lower courts on how to assess the source, content, and context of adverse event reports under the "something more" standard. Some corporations may be incentivized to disclose unnecessary information, rather than risk miscalculation of materiality and potentially costly litigation.¹²³ Such disclosures of non-material data conflict with the Court's longstanding concern against "bury[ing] the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking"¹²⁴ The Court's silence on how to apply the "something more" standard creates confusion for companies and courts and further complicates an already intricate "total mix" analysis.¹²⁵ The *Matrixx* decision is, therefore, more likely to hinder than foster informed investor decision-making.

116. *Minneapolis Firefighters' Relief Ass'n v MEMC Electronic Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (finding the plaintiff failed to plead actionable omission or scienter).

117. *Id.* at 1029.

118. See e.g., *Local 731 I.B. of T. Excavators and Pavers Pension Trust Fund v. Swanson*, No. 09-799, 2011 WL 2444675, at *6 (D. Del. June 14, 2011) (stating that *Matrixx* "endorses a generous application of the PSLRA with respect to pleading materiality and scienter under Section 10(b) and Rule 10b-5").

119. *Id.*

120. *Id.* at *9-10. "Puffery is a 'vague statement of corporate optimism' that is said to be 'so obviously unimportant to a reasonable investor that reasonable minds could not differ.'" David A. Hoffman, *The Best Puffery Article Ever*, 91 IOWA L. REV. 1395, 1405-06 (2006).

121. No. 08-2348, 2011 U.S. Dist. LEXIS 126436 (D. S.C. Oct. 19, 2011).

122. *Id.* at *59-60.

123. See *infra* Part IV.A.

124. See *infra* note 44 and accompanying text. The FDA's engagement in a robust drug approval regulation, balancing the benefits of drug approval against the cost of adverse reactions, along with their recent trend towards greater informational inputs on adverse event reports, makes it unlikely the agency will attempt to provide a framework or additional guidance to corporations. See *infra* notes 94-102 and accompanying text.

125. See David H. Kaye, *supra* note 4, at 1 ("The case offered the Supreme Court an opportunity to speak clearly and authoritatively about the meaning and limits of significance testing. Unfortunately, the Court did not rise to this challenge."); and Dale A. Oesterle, *The Overused and Under-Defined Notion of "Material" in Securities Law*, 14 U. PA. J. BUS. L. 167, 184 (2011) (noting the court's failure to address existing complexities in the materiality standard).

V. CONCLUSION

In *Matrixx Initiatives, Inc. v. Siracusano*,¹²⁶ the United States Supreme Court decided a plaintiff is not required to allege “statistical significance” in a securities fraud claim for failure to disclose adverse events.¹²⁷ In so holding, the Court correctly determined the plaintiff sufficiently pled materiality and scienter.¹²⁸ Given the complexities of applying the standard of materiality to the facts in any case, however, the Court missed an opportunity to provide clear guidance to business entities and to lower courts.¹²⁹

126. 131 S. Ct. 1309 (2011).

127. *See infra* Part III.

128. *Id.*

129. *See infra* Part IV.