

THE SIGNIFICANCE OF IT ALL: CORPORATE DISCLOSURE OBLIGATIONS IN *MATRIXX INITIATIVES, INC. v.* *SIRACUSANO*

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I. INTRODUCTION

Physicians or consumers of pharmaceutical products can file complaints with the manufacturing company or with the Food and Drug Administration (FDA) to report adverse events that occurred after use. When the FDA receives the complaint, the agency may decide that an investigation into the drug's safety is warranted.¹ Announcements of FDA investigations into drug safety may result in a drop in the manufacturing company's stock price.² Prior to 2006, when consumers complained directly to the company, homeopathic drug companies were not required to report these complaints to the FDA.³ *Matrixx Initiatives, Inc. v. Siracusano*⁴ addresses whether a drug company violated securities-law disclosure requirements by failing to disclose these complaints to its shareholders. Section 10(b) of the Securities Exchange Act of 1934⁵ and Securities Exchange

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1. Brief for Petitioners at 22–23, *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. Aug. 20, 2010).

2. See Brief for the United States as Amicus Curiae Supporting Respondents at 18, *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. Nov. 12, 2010) (“Such regulatory attention can have a significant impact on a drug's commercial success and litigation risk.”).

3. Brief for Respondents at 9, *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. Nov. 5, 2010). In 2006, Congress enacted a statute requiring the manufacturers of homeopathic drugs to report serious adverse events to the FDA. The Dietary Supplement and Nonprescription Drug Consumer Protection Act, 21 U.S.C.A. §379aa (West 2011).

4. *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. argued Jan. 10, 2010).

5. Securities Exchange Act of 1934, 15 U.S.C.A. § 78j(b) (West 2011).

Commission (SEC) Rule 10b-5⁶ require corporations to disclose material information to their shareholders. *Matrixx Initiatives* concerns whether adverse-event reports are material information under this rule when the reports do not demonstrate a statistically significant link between drug use and adverse events.⁷

II. FACTS

Matrixx Initiatives, Inc. (Matrixx) is a pharmaceutical company whose wholly-owned subsidiary, Zicam, LLC, produces and markets a homeopathic cold remedy called Zicam Cold Remedy (Zicam).⁸ Zicam can be administered intranasally through a spray or gel, and its active ingredient is zinc gluconate.⁹ Prior to placing the drug on the market, Matrixx had conducted two clinical trials of Zicam with no indication of any statistically significant safety issues.¹⁰ In 1999, a doctor reported to Matrixx that his patient had developed anosmia, the loss of smell, after using Zicam intranasally.¹¹ The doctor also informed Matrixx that studies had shown that the intranasal application of zinc compounds can produce anosmia and offered to study a possible link between Zicam and anosmia.¹² In 2002, Matrixx's Vice President of Research and Development, Timothy Clarot (Clarot), contacted a scientist whose patient had complained to

6. SEC Rule 10b-5, 17 C.F.R. § 240.10b-5(b) (2011).

7. Brief for Petitioners, *supra* note 1, at i.

8. *Siracusano v. Matrixx Initiatives, Inc. (Matrixx I)*, No. CV 04 0886 PHX MHM, 2005 WL 3970117, at *1 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 3411 (2010).

9. *Matrixx Initiatives, Inc. v. Siracusano (Matrixx II)*, 585 F.3d 1167, 1170 (9th Cir. 2009).

10. Brief for Petitioners, *supra* note 1, at 5. While homeopathic drugs must meet strength, quality, and purity standards, the FDA does not subject them to the rigorous safety and efficacy requirements that other medicinal drugs must meet. Conditions Under Which Homeopathic Drugs May Be Marketed, FDA Compliance Policy Guide § 400.400 (1995), <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>. Statistical significance can be summarized as follows:

To assess statistical significance in the medical context, a researcher begins with the 'null hypothesis,' i.e., that there is no relationship between the drug and the adverse effect. The researcher calculates a 'p-value,' which is the probability that the association observed in the study would have occurred even if there were in fact no link between the drug and the adverse effect. If that p-value is lower than the 'significance level' selected for the study, then the results can be deemed statistically significant.

Brief for the United States, *supra* note 2, at 13.

11. *Matrixx II*, 585 F.3d at 1170.

12. *Id.*

Matrixx of anosmia after using Zicam.¹³ The scientist subsequently sent Clarot information about polio studies from the 1930s linking zinc sulfate to anosmia.¹⁴ Clarot asked the scientist if she would participate in animal studies of Zicam, but she declined.¹⁵ In 2003, Dr. Bruce Jafek prepared a presentation to the American Rhinologic Society studying ten patients who took Zicam prior to losing their sense of smell.¹⁶ Matrixx informed Dr. Jafek that he could not use the names “Matrixx” or “Zicam” in his presentation¹⁷ and asked for more information about the possible link.¹⁸

Despite receiving notifications of a potential link between using Zicam and developing anosmia, Matrixx “continued to make positive statements regarding Matrixx’s growth and revenue and Zicam’s safety” without disclosing the possible link to shareholders.¹⁹ In its press releases and an earnings conference call, Matrixx touted Zicam’s potential for growth and efficacy.²⁰ In a filing with the SEC, Matrixx warned of the risk and consequences of possible product-liability litigation, but did not disclose that a lawsuit had been filed already alleging that Zicam caused loss of smell.²¹

On January 30, 2004, a news article reported that three lawsuits had been filed against Matrixx and that the FDA was investigating a possible link between Zicam and anosmia.²² Over the next two days, Matrixx’s stock price fell from \$13.55 to \$11.97.²³ Matrixx responded by issuing a press release declaring that “statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.”²⁴ The company also stated that the drug’s safety and efficacy had been established in two clinical

13. *Id.*

14. *Id.*; Brief for Petitioners, *supra* note 1, at 6.

15. *Matrixx II*, 585 F.3d at 1170.

16. *Id.* at 1171.

17. *Id.* While the Ninth Circuit appeared to believe that Matrixx’s refusal to grant permission for Jafek to use the name “Zicam” in his presentation lends support to Matrixx’s having the requisite scienter under Rule 10b-5, *id.* at 1182, Matrixx’s refusal might have been merely a strategic precaution protecting its trademark from possible bad publicity or slander.

18. Brief for Petitioners, *supra* note 1, at 7.

19. *Siracusano v. Matrixx Initiatives, Inc. (Matrixx I)*, No. CV 04 0886 PHX MHM, 2005 WL 3970117, at *1 (D. Ariz. Dec. 15, 2005), *rev’d*, 585 F.3d 1167 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 3411 (2010).

20. *Id.*

21. *Matrixx II*, 585 F.3d at 1172.

22. *Id.*

23. *Id.*

24. *Id.* at 1173 (quoting Press Release, Matrixx Initiatives, Inc. (Feb. 2, 2004)).

trials.²⁵ The next day, Matrixx's stock price rose to \$13.40.²⁶ On February 6, Good Morning America reported on the possible link between Zicam and anosmia, and the stock price fell even more dramatically—from \$13.05 on February 5 to \$9.94 on February 6.²⁷ Matrixx again denied the allegations that Zicam caused anosmia in a press release, reiterating that the drug had been tested in two clinical trials without any reports of anosmia.²⁸ In another SEC filing a few weeks later, however, Matrixx stated that a panel of scientists had concluded that “insufficient scientific evidence [was available] at this time to determine if zinc gluconate, when used as recommended, affects a person’s ability to smell.”²⁹

In April 2004, Siracusano brought a class action suit against Matrixx under the Private Securities Litigation Reform Act of 1995 (PSLRA).³⁰ The PSLRA permits private individuals to sue on behalf of all who invested in a particular company during a stated period of time to enforce federal securities laws.³¹ Siracusano sued on behalf of all investors in Matrixx between October 22, 2003, and February 6, 2004 (the Class Period).³² Siracusano alleged that Matrixx violated Rule 10b-5 by not disclosing the risk that Zicam causes anosmia and by issuing false and misleading statements.³³ The district court granted Matrixx's motion to dismiss and Siracusano appealed.³⁴ The Ninth Circuit reversed the district court's dismissal, holding that materiality under Rule 10b-5 does not require statistical significance, and thus Siracusano had “sufficiently pled materiality to survive dismissal.”³⁵ In June 2009, several years after this litigation began and after the Class Period, the FDA issued a warning letter to Matrixx stating that Zicam might pose a safety risk to consumers.³⁶

25. *Id.*

26. *Id.* at 1174.

27. *Id.*

28. *Id.*

29. *Id.* (quoting Form 8-K Filing, Matrixx Initiatives, Inc. (Feb. 19, 2004)).

30. Private Securities Litigation Reform Act of 1995, 15 U.S.C.A. §§ 77–78 (West 2010).

31. *Id.*

32. *Matrixx II*, 585 F.3d at 1170.

33. *Id.*

34. *Id.* at 1177.

35. *Id.* at 1183.

36. *Id.* at 1169 n.1.

III. LEGAL BACKGROUND

Section 10(b) of the Securities Exchange Act of 1934 implements a “philosophy of full disclosure”³⁷ and authorizes the Securities and Exchange Commission to promulgate rules prohibiting “manipulative or deceptive” practices “in connection with the purchase or sale of any security.”³⁸ Under Rule 10b-5, it is unlawful 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.”³⁹ To prove a violation, a plaintiff must show “(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.”⁴⁰ As the district court dismissed the case based on Siracusano’s failure to allege sufficient materiality and scienter, only these elements are at issue in this case.⁴¹ Under the PSLRA, Congress codified a private right of action for violations of Securities Exchange Act section 10(b) and established heightened pleading requirements.⁴² The PSLRA requires plaintiffs to identify and explain each misleading statement and allege facts “giving rise to a strong inference” of scienter.⁴³

A. Materiality

In *TSC Industries, Inc. v. Northway, Inc.*,⁴⁴ the Supreme Court clarified the standard for determining whether an omission of fact is material in federal securities law cases.⁴⁵ *TSC Industries* concerned Securities Exchange Act section 14(a) and SEC Rule 14a-9, which prohibit the omission of material facts in proxy statements.⁴⁶ In *TSC Industries*, the Court balanced the purpose of the proxy regulations—to encourage corporate management to disclose pertinent

37. *Basic Inc. v. Levinson*, 485 U.S. 224, 230 (1988) (quoting *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 477–78 (1977)).

38. Securities Exchange Act of 1934, 15 U.S.C.A. § 78j(b) (West 2011).

39. SEC Rule 10b-5, 17 C.F.R. § 240.10b-5(b) (2011).

40. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005).

41. *Matrixx II*, 585 F.3d at 1177.

42. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 320–21 (2007); Private Securities Litigation Reform Act, 15 U.S.C.A. §§ 77–78 (West 2010).

43. 15 U.S.C.A. § 78u-4(b) (West 2010).

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

45. *Id.* at 443.

46. 17 C.F.R. § 240.14a-9 (2011).

information to keep shareholders informed in their investment decisions⁴⁷—against the concern that disclosures could hurt, rather than help, shareholders in some situations.⁴⁸ For example, in its attempt to reduce potential liability, management might over-disclose and “bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking.”⁴⁹ The Court thus held that the appropriate standard of materiality requires “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.”⁵⁰

The Supreme Court applied the materiality standard set out in *TSC Industries* to section 10(b) and Rule 10b-5 in *Basic Inc. v. Levinson*.⁵¹ *Basic Inc.* addressed whether a preliminary merger discussion was material under Rule 10b-5.⁵² In that case, Basic Inc., a publicly traded company, had publicly denied its involvement in merger negotiations even though its officers and directors met with another company about a possible merger during that time.⁵³ After the merger was approved, former shareholders who sold their shares after Basic’s denials sued the company alleging that its statements violated Rule 10b-5.⁵⁴

The *Basic* Court expressly adopted the *TSC Industries* test for determining materiality under Rule 10b-5.⁵⁵ The Court settled on this “highly fact-dependent probability/magnitude” test as the correct approach to determining the materiality of “contingent or speculative information or events,” such as merger negotiations.⁵⁶ Emphasizing that the significance of the information is necessary to a finding of materiality, the Court noted that it is insufficient to find merely that the information was false or incomplete.⁵⁷ In rejecting a bright-line rule, the Court emphasized that materiality requires “an inherently fact-specific finding” and that although such a rule might be easy to

47. *TSC Indus.*, 426 U.S. at 448.

48. *Id.*

49. *Id.* at 448–49.

50. *Id.*

51. *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988).

52. *Id.* at 226.

53. *Id.* at 227.

54. *Id.* at 227–28.

55. *Id.* at 232–33, 237.

56. *Id.* at 238, 239 n.16.

57. *Id.* at 238.

apply, it is always over or underinclusive.⁵⁸ The Court reiterated that materiality requires an assessment of the facts and rejected “confining [it] to a rigid formula.”⁵⁹

B. Scierter

The PSLRA requires a plaintiff to plead facts that give rise to a “strong inference that the defendant acted with the required state of mind.”⁶⁰ In *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*,⁶¹ the Supreme Court clarified the meaning of “strong inference” in response to a split among the circuit courts.⁶² The *Tellabs* Court held that when determining whether allegations provide a strong inference, courts must view them as a whole and “consider plausible nonculpable explanations” as well.⁶³ Most importantly, the Court held that a complaint will allege sufficient scierter only where the facts give rise to an inference of scierter as “cogent and at least as compelling as any opposing inference.”⁶⁴

IV. HOLDING

In *Matrixx Initiatives*, the Ninth Circuit held that the district court erred in relying on a statistical significance standard to reject, as a matter of law, Siracusano’s allegations of materiality and scierter under Rule 10b-5.⁶⁵ It concluded that requiring a standard of statistical significance in the materiality determination would contradict the Supreme Court’s holding in *Basic*.⁶⁶ The *Basic* Court stated that assessing materiality involves a “fact-specific inquiry” and rejected the application of a “bright-line rule” to materiality determinations.⁶⁷ As a result, the Ninth Circuit determined that dismissing a case based solely on the failure of the plaintiff to plead statistical significance would cut against *Basic* by both enforcing a bright-line rule and violating the principle that the trier of fact should

58. *Id.* at 233, 236.

59. *Id.*

60. 15 U.S.C.A. § 78u-4(b)(2) (West 2010).

61. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007).

62. *Id.* at 322.

63. *Id.* at 323–24.

64. *Id.* at 324.

65. *Matrixx Initiatives, Inc. v. Siracusano (Matrixx II)*, 585 F.3d 1167, 1178 (9th Cir. 2009).

66. *Id.*

67. *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988).

assess materiality.⁶⁸ The Ninth Circuit held that there is no statistical significance requirement to state a claim of material omission, and thus Siracusano's failure to allege statistical significance would not bar a trier of fact from finding that Matrixx's omissions were material.⁶⁹

Accordingly, the Ninth Circuit conducted a fact-specific inquiry to decide whether a reasonable investor would have considered information about the possible link between Zicam and anosmia significant.⁷⁰ In making this determination, the court considered that physicians reported the user complaints, that Matrixx knew of studies demonstrating a link between intranasal application of zinc compounds and development of anosmia, that Matrixx was aware of case studies indicating that patients developed anosmia after using Zicam, and that lawsuits against Matrixx alleging that Zicam causes anosmia were pending.⁷¹ In light of these facts, the court held that Siracusano adequately alleged that Matrixx's nondisclosure of adverse-event reports was material.⁷²

The Ninth Circuit also held that the facts pled in the complaint enabled a reasonable person to infer that Matrixx had the requisite scienter.⁷³ Despite no indication that the adverse-event reports were statistically significant, the court determined that "the inference of scienter is 'cogent and at least as compelling' as any 'plausible non-culpable explanation[]' for [Matrixx's] conduct."⁷⁴

V. ARGUMENTS

A. *Matrixx's (Petitioner's) Argument*

Matrixx argues that the adverse-event reports it received are not material and that no strong inference of deceit can be made because Siracusano's complaint does not assert that these reports are statistically significant. Without statistical significance, nothing

68. *Matrixx II*, 585 F.3d at 1183.

69. *Id.* at 1179–80.

70. *Id.* at 1179.

71. *Id.*

72. *Id.* at 1179–80.

73. *Id.* at 1183.

74. *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)).

indicates a causal relationship, and thus Siracusano failed to sufficiently allege materiality and scienter.⁷⁵

First, Matrixx claims that the complaints it received and failed to disclose during the Class Period are not material within the meaning of SEC Rule 10b-5.⁷⁶ In effect, Matrixx argues that no reasonable investor would consider adverse-event reports to “significantly alter[] the total mix of information” available, unless they indicate that the drug users’ incidence of adverse events is statistically significant as compared to non-drug users’ incidence of adverse events.⁷⁷ As adverse-event reports include “any anecdotal report that the user of a drug experienced an adverse event at some point during or following the use of that drug” and they are “inherently unreliable,” such reports do not show a causal relationship between drug use and the adverse event.⁷⁸ Additionally, people with the common cold, Zicam’s target population, are more likely to develop anosmia in the first place.⁷⁹ This increased incidence suggests that even if Zicam users’ rate of adverse events is higher than that of the general population, this could be due to preexisting illness.⁸⁰

Matrixx argues that compelling the disclosure of adverse-event reports, absent some statistically significant evidence of a causal relationship, would “inundate[e] the market with useless, trivial, and even affirmatively misleading information, which will only undermine reasoned investment decisionmaking.”⁸¹ Since the reports provide only unreliable and speculative information, reasonable investors would not use them to make investment decisions.⁸² Furthermore, to avoid potential liability for securities fraud, pharmaceutical companies will react by disclosing all adverse-event reports.⁸³ This will force investors to sift through unnecessary and unreliable information when making their investment decisions without providing any reasonable way for them to determine when products face legitimate safety concerns.⁸⁴ By inundating consumers with adverse-event

75. Brief for Petitioners, *supra* note 1, at 15–16.

76. *Id.* at 15.

77. *Id.* at 26 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)).

78. *Id.* at 17, 20.

79. *Id.* at 15.

80. *Id.*

81. *Id.* at 26.

82. *Id.*

83. *Id.* at 29–30.

84. *Id.*

reports—thus hiding truly important information in a sea of insignificant and trivial information—this type of compelled disclosure would undermine the purpose of the materiality requirement.⁸⁵

Second, Matrixx maintains that investors care about the existence of a causal relationship between drug use and adverse-health events, which are not speculative and are unreliable allegations of a link. Statistically significant evidence of causation must be required before a company discloses adverse-event reports.⁸⁶ Scientists use statistical significance to measure the degree of association between two events, or put differently, whether two events “occur together more frequently than one would expect by chance.”⁸⁷ Courts also use statistical significance in some legal contexts, such as product liability and toxic torts, to provide evidence of causation.⁸⁸ Because statistical significance distinguishes between the random coincidence of two events and a nonrandom association between those events, this standard “defines” what information is relevant to a reasonable investor.⁸⁹

According to Matrixx, relying on a statistical significance standard for materiality would provide guidance both for investors in making investment decisions related to product-safety risks, and for companies about what information they are obligated to disclose.⁹⁰ Other than this standard, “there is no intelligible basis” for understanding when the drug, and not other factors, causes adverse events.⁹¹ To sufficiently plead the materiality of omitted facts, a plaintiff should be required to allege facts demonstrating a statistically significant increase in the incidence of adverse events reported by drug users over the incidence of adverse events in the population suffering from the target condition.⁹² The complaint should fail as a matter of law because Siracusano did not allege that consumer complaints showed a statistically significant increase

85. *Id.*

86. *Id.* at 32–33.

87. *Id.* at 34 (quoting Michael D. Green et al., *Reference Guide on Epidemiology*, in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 354–58 (2d ed. 2000)).

88. *Id.* at 36–37.

89. *Id.* at 43.

90. *Id.* at 44.

91. *Id.* at 49.

92. *Id.* at 42.

between the rate of anosmia among the general population or cold-sufferers and the rate among Zicam users.⁹³

In addition to failing to adequately allege materiality, Matrixx argues that Siracusano did not sufficiently plead scienter.⁹⁴ The complaint does not plead facts that give rise to a strong inference of an intention to deceive, that is, an inference that is “cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”⁹⁵ First, because adverse-event reports generally are unreliable and provide speculative information, one cannot infer that Matrixx believed this information was material and warranted disclosure.⁹⁶ Second, because the adverse-event reports received by Matrixx do not show a statistically significant increase in anosmia among Zicam users compared to cold-sufferers in general, an inference that Matrixx had the requisite scienter is not as compelling as other inferences.⁹⁷ In fact, the “most obvious inference” is that Matrixx did not disclose the adverse-event reports because it did not believe they “indicate[d] anything meaningful about adverse reactions to [the] use of Zicam.”⁹⁸ Therefore, Siracusano’s complaint failed to sufficiently allege the presence of scienter.⁹⁹

B. Siracusano’s (Respondent’s) Arguments and Supporting Arguments by the United States as Amicus Curiae

Siracusano argues that the Supreme Court should affirm the Ninth Circuit’s holding that statistical significance is not required to allege the materiality of omitted adverse-event reports. A finding of materiality in securities-fraud cases requires a factual inquiry.¹⁰⁰ Requiring a statistical significance standard would impose the type of bright-line rule that the Supreme Court rejected in *Basic*.¹⁰¹ Additionally, the facts demonstrate that Matrixx acted with intentional deceit or recklessness by failing to disclose consumer complaints and by making statements about the safety of Zicam.¹⁰²

93. *Id.* at 45.

94. *Id.* at 49.

95. *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)).

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* at 51.

100. Brief for Respondents, *supra* note 3, at 21–22.

101. *Id.*

102. *Id.* at 22.

First, because the standard for materiality requires determining whether the reasonable investor would consider the omitted facts to “significantly alter[] the ‘total mix’ of information made available,”¹⁰³ Siracusano emphasizes the necessity of a factual inquiry.¹⁰⁴ Considering this fact-specific determination, materiality should be decided on the evidence, not at the pleading stage, and therefore the case should proceed to trial.¹⁰⁵ The facts show that causation between Zicam use and anosmia is more than plausible—doctors (not merely consumers alone) have pinpointed a possible connection, patients felt a burning feeling after using Zicam, and studies have shown that another zinc compound causes anosmia.¹⁰⁶ Matrixx had knowledge of these facts prior to the commencement of the Class Period and thus withheld information that a reasonable investor would find significant.¹⁰⁷ Additionally, Matrixx misled the public about the extent of scientific study on whether Zicam use causes anosmia by making affirmative statements that it was safe.¹⁰⁸

Second, Siracusano argues that requiring statistical significance to prove materiality would depart from Supreme Court precedent, creating an underinclusive materiality determination that leaves out numerous considerations that a reasonable investor would deem important.¹⁰⁹ Statistical significance is a poor indicator of the practical importance of information to a reasonable investor because it is not error free and does not “incorporate either the *magnitude* or the *implications* of a study’s result.”¹¹⁰ The statistical significance standard is analogous to the bright-line rule rejected in *Basic* in that a categorical rule of statistical significance would allow pharmaceutical companies to withhold information that reasonable investors would deem significant.¹¹¹ Although courts should consider statistical significance before trial, that standard should not prevent the parties from having their day in court because investors consider many factors when making a decision.¹¹²

103. TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976).

104. Brief for Respondents, *supra* note 3, at 25–26.

105. *Id.* at 27–28.

106. *Id.* at 28–29.

107. *Id.* at 28.

108. *Id.* at 31–32.

109. *Id.* at 39–41.

110. *Id.* at 38–40.

111. *Id.* at 41.

112. *Id.* at 45–47.

Siracusano argues that, viewing the allegations as a whole, the complaint gives rise to a strong inference of scienter.¹¹³ Considering Matrixx was “well aware of the potential risk that the doctors’ findings posed to its products” and failed to disclose this information, an inference that Matrixx intentionally deceived or recklessly withheld information is just as compelling as any other inference.¹¹⁴ Additionally, Matrixx’s statements about Zicam’s “well established” safety and its “reluctant admissions” that there was insufficient scientific evidence to determine whether Zicam use is linked to anosmia, lead to a compelling inference of scienter.¹¹⁵

The United States supports the Ninth Circuit’s holding that Siracusano sufficiently pled materiality and scienter.¹¹⁶ It reiterates Siracusano’s position that reasonable investors do not limit investment decisions only to information showing a statistically significant association between drug use and adverse events.¹¹⁷ The government suggests that statistical significance is a limited tool and is only one of many that can be used to determine causation.¹¹⁸ Investors should not be restricted to statistically significant information because information suggesting possible adverse effects can alter investor and regulatory behavior, which in turn could affect a company’s share price.¹¹⁹ The United States also argues the statistical significance standard conflicts with *Basic*’s emphasis on a factual inquiry and rejection of a bright-line rule, and therefore should not bar a trial.¹²⁰

VI. ANALYSIS AND LIKELY DISPOSITION

The Ninth Circuit’s rejection of the statistical significance standard in determining materiality under Rule 10b-5 created a circuit split. The Second Circuit first established the statistical significance standard in this context in *In re Carter-Wallace*.¹²¹ In holding that a drug company was not obligated to disclose deaths related to drug use, the Second Circuit stated that adverse-event reports need not be disclosed until they show statistically significant

113. *Id.* at 34–35.

114. *Id.* at 36.

115. *Id.* at 37.

116. Brief for the United States as Amicus Curiae, *supra* note 2, at 11.

117. *Id.* at 11–12.

118. *Id.* at 13.

119. *Id.* at 17.

120. *Id.* at 22–23.

121. *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998).

evidence of a nonrandom association and are serious enough to affect the drug's prospective earnings.¹²² The Third Circuit (in an opinion authored by then-Judge Alito) subsequently adopted this standard in *Oran v. Stafford*,¹²³ holding that it was not materially misleading to withhold data where a causal link had not been conclusively ascertained.¹²⁴ Finally, the First Circuit relied on the statistical significance standard to determine that a drug company lacked the requisite scienter under Rule 10b-5, assuming that the plaintiffs met the materiality standard.¹²⁵ Thus, due to the Ninth Circuit's departure from the other circuit courts' decisions, this issue is ripe for clarification by the Supreme Court.

Whether materiality under Rule 10b-5 should require a showing of statistical significance rests primarily on how one views the corporate disclosure obligations embedded in federal securities laws. The most apparent difficulty with this case is that each side's arguments appear to fulfill the purpose behind these laws and Rule 10b-5 in particular. The standard set forth in *TSC Industries* states that an omission or misstatement is material only where a reasonable investor would deem it to "significantly alter[] the 'total mix' of information made available."¹²⁶ While the purpose of Rule 10b-5 is to encourage the full disclosure of information to shareholders, the purpose of the materiality requirement is to weed out insignificant and trivial information from a company's disclosure obligation.¹²⁷ The requirement seeks to encourage companies to be open with their investors but, at the same time, not flood them with insignificant information that would make it overly burdensome to determine what information is important.¹²⁸ Therefore, there is an inherent tension. *Matrixx* and *Siracusano* represent opposite sides of this tension. *Siracusano* wants companies to disclose possibly insignificant adverse-event reports, whereas *Matrixx* wants to disclose only information that demonstrates a statistically significant link. The Supreme Court must decide, therefore, whether requiring disclosure of adverse-event reports absent statistical significance ultimately

122. *Id.*

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

124. *Id.* at 284.

125. *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 47 (1st Cir. 2008).

126. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

127. *Id.* at 448-49; *Basic Inc. v. Levinson*, 485 U.S. 224, 234 (1988).

128. *TSC Indus.*, 426 U.S. at 448-49.

would disrupt the delicate balance between disclosing too little and disclosing too much information.

One of the issues raised by this case is the application of scientific phenomena to law. The premise of a statistical significance calculation is to determine whether two or more events have occurred together by chance or whether that occurrence is unlikely to occur randomly.¹²⁹ Statistical significance alone does not suggest causation—it indicates correlation.¹³⁰ But where facts do not rise to the level of statistical significance, this means a correlative relationship between two events is highly unlikely.¹³¹ Thus, where adverse-event reports are not statistically significant, there is likely no correlation between drug use and adverse events—let alone a causal relationship. Theoretically, information that is not statistically significant would not have any effect on investment decisions because there is no scientifically proven basis for concern.

Despite the apparent applicability of statistical significance to whether adverse-event reports are material to investors and should be disclosed by pharmaceutical companies, Siracusano argues that the imposition of such a standard would depart from Supreme Court precedent. *Basic*'s rejection of a bright-line rule suggests that a rule like that proposed by Matrixx would impinge on the factual inquiry that must be conducted in determining materiality.¹³² In this inquiry, one should assess whether a reasonable investor would consider information important in deciding whether to buy or sell stock.

Requiring a statistical significance standard at the pleading stage would bar cases from trial unless adverse-event reports were statistically significant. No other factors relevant to the materiality inquiry would be considered absent reaching an initial threshold of statistical significance. These factors might include those ensuring that safety complaints are legitimate, such as who reported the adverse event (i.e., a doctor or a patient) and the type and extent of adverse effects, as well as factors suggesting a causal link. This would keep many Rule 10b-5 plaintiffs out of court, thus permitting companies to not disclose safety issues when investors might want to know about them regardless of statistical significance. Matrixx's argument that

129. Brief for Petitioners, *supra* note 1, at 34–36.

130. *Id.*

131. *Id.*

132. See *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988) (rejecting a “bright-line rule” because materiality is an “inherently fact-specific finding”).

investors would not consider adverse-event reports to be material unless they showed a statistically significant increase in the rate of adverse events might be credible if investors cared only about whether the drug actually *caused* the adverse events. Investors, however, care about the market for their shares,¹³³ which is affected by many factors, not just whether actual causation exists. Thus, the materiality determination does not hinge solely on whether evidence of a causal link between drug use and adverse events is available.

Nevertheless, as alluded to by Justice Scalia in oral argument, it seems absurd to determine materiality by deciding what information a reasonable investor thinks would cause unreasonable investors to do with their shares and how this would affect the market.¹³⁴ The inquiry should be whether a reasonable investor would consider the information to “significantly alter[] the ‘total mix’ of information.”¹³⁵ In other words, would reasonable investors believe that a smattering of adverse-event reports is indicative of larger problems within a pharmaceutical company? The statistical significance standard would provide investors in pharmaceutical companies with information that they could know has some substance to it—information that would provide a meaningful basis for concern about the company’s state of affairs.

Given the *Basic* Court’s rejection of relying on a bright-line rule to determine whether information is material under Rule 10b-5, it probably will affirm the Ninth Circuit’s rejection of requiring statistical significance to show materiality. If required, this standard would bar many plaintiffs from reaching the factual inquiry that is required for determining materiality. Factors other than the statistical significance of adverse events are relevant to investment decisions affecting the market. Thus, adverse-event reports that fail to demonstrate statistically significant causal links between drug use and adverse events may be material nevertheless, and corporations might need to disclose them to shareholders.

Although both sides have strong arguments in their favor,

133. See Transcript of Oral Argument at 8, *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. Jan. 10, 2010) (Chief Justice Roberts noted that if he were an investor in *Matrixx*, he would “worry whether [his] stock price is going to go down.”).

134. See *id.* at 39 (“[I]t seems to me ridiculous to . . . hold companies to . . . irrational standards.”). But see *id.* at 16 (“A reasonable investor is going to worry about the fact that thousands of unreasonable investors are going to dump their *Matrixx* stock.”) (Roberts, C.J.).

135. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

Siracusano likely will prevail. Whereas Matrixx argues for a clearer rule that would provide investors with a legitimate basis for concern when information about adverse events is disclosed,¹³⁶ Siracusano's rule more clearly adheres to Supreme Court precedent.¹³⁷ It encourages pharmaceutical companies to disclose more information to their investors—information that reasonable investors would consider relevant in their decision-making process.¹³⁸

At oral argument, the Court focused on determining why it should apply the statistical significance standard and whether factors other than statistical significance matter, perhaps indicating a preference for proceeding with a factual inquiry rather than applying a hard-and-fast rule. The Court also attempted to discern where the boundary between materiality and nonmateriality would lie in cases involving adverse-event reports absent a statistical significance standard. This suggests that the Court may seek to clarify the law without imposing the strict standard of statistical significance.

Chief Justice Roberts, and Justices Ginsburg, Sotomayor, and Kagan appeared to dislike the idea of imposing statistical significance as a matter of law and were skeptical of why the Court should not permit cases to proceed straight to trial. The Chief Justice emphasized that the causal link between Zicam and anosmia would not be the sole issue about which investors would be concerned, and that the relevant consideration includes how different types of information will affect the market.¹³⁹ Questioning why the Court should not just allow cases such as this to proceed to a factual determination at trial, Justices Ginsburg and Sotomayor also implied that information other than mere statistical data would be important to investors, including information about who reports the adverse events and the substance of these complaints.¹⁴⁰ Justice Kagan suggested that investors would

136. See Brief for Petitioners, *supra* note 1, at 44 (“Statistical significance also gives both companies *and* investors guidance they need to understand corporate disclosure obligations. . . . Statistical significance is a perfectly intelligible basis for distinguishing material from immaterial [adverse event reports] . . .”).

137. See Brief for Respondents, *supra* note 3, at 41 (“In *Basic*, this Court declined to adopt a ‘usable, bright-line rule’ . . .” (quoting *Basic*, 485 U.S. at 232–33)).

138. See *id.* at 47 (“In assessing the risk of a particular drug causing an important adverse effect, a reasonable investor would consider a broad range of different kinds of information.”).

139. Transcript of Oral Argument, *supra* note 133, at 7–8, 16. For example, the Chief Justice stated that “[y]ou can have some psychic come out and say ‘Zicam is going to cause a disease’ with no support whatsoever, but if it causes the stock to go down [twenty] percent, it seems to me that’s material.” *Id.* at 8.

140. See *id.* at 4 (“But why shouldn’t that determination be deferred until there’s discovery,

still want to know about adverse events even in situations where the events are not statistically significant but nonetheless suggest a causal link.¹⁴¹ Justice Kagan also noted that the FDA looks to other factors than statistical significance, not requiring adverse-event reports to demonstrate a statistically significant increase in adverse events before it initiates an investigation or issues warning letters.¹⁴² Rejecting the statistical significance standard during oral argument, Justice Breyer suggested that lack of scientific proof does not mean that something is not significant.¹⁴³ He explained that many great scientific theories are relevant and important before they are empirically proven.¹⁴⁴

Even assuming the statistical significance standard would be the only issue important to investors, several Justices appeared to reject the standard for other reasons. Justice Breyer inferred that judges do not know when adverse-event reports suggest something important about the company, and so should not impose a strict standard.¹⁴⁵ Congress, Justice Breyer intimated, should institute the statistical significance standard if it believes that standard adequately reflects when information is material to investors.¹⁴⁶ Justice Sotomayor pointed to Matrixx's apparent concession that the statistical significance standard cannot be absolute in all circumstances.¹⁴⁷

Appearing to support the statistical significance standard, Justices Scalia and Alito most likely would side with Matrixx. Justice Scalia appeared to reject the idea that companies should have to be concerned with how irrational or unreasonable investors would react when disclosing information, saying that is not what the Court meant in *Basic*.¹⁴⁸ Both Justices Scalia and Alito questioned what sort of affirmative statements a company must make to trigger a duty to disclose the adverse-event reports.¹⁴⁹ Chief Justice Roberts also expressed some qualms about rejecting the standard and suggested that pharmaceutical companies would have difficulty keeping

and then we can know how many reports there really were?") (Ginsburg, J.); *id.* at 8.

141. *Id.* at 17–18.

142. *Id.* at 12–13.

143. *Id.* at 20–21.

144. *Id.*

145. *Id.* at 20.

146. *Id.*

147. *Id.* at 24.

148. *Id.* at 39.

149. *Id.* at 48–50.

unmeritorious suits from going to trial absent the statistical significance standard.¹⁵⁰

Given *Basic*'s rejection of a "bright-line rule" when determining the materiality of information for purposes of securities-disclosure requirements, the Court probably will hold that Matrixx's proposed statistical significance standard is too rigid for the analysis and side with Siracusano. Many adverse-event reports are made directly to the pharmaceutical company and might not be known to plaintiffs prior to discovery, which enables plaintiffs to learn about problems that might be necessary to establishing a statistically significant correlation. If the Court required plaintiffs to show statistical significance as a threshold matter, many litigants would never have the information necessary to allege the facts required under this standard.

Additionally, the Court has deferred to the SEC in the past when interpreting federal securities laws and rules, and the SEC supports Siracusano's position here. The Court will likely defer again to the SEC's judgment and hold that the materiality of adverse events does not require showing statistical significance.¹⁵¹ Given his decision in *Oran v. Stafford*,¹⁵² Justice Alito, along with Justice Scalia, however, likely will dissent in favor of requiring plaintiffs to show statistical significance to meet Rule 10b-5's materiality requirement.

In sum, *Matrixx Initiatives, Inc. v. Siracusano* concerns whether adverse events reported to a drug company constitute material information that must be disclosed to shareholders under SEA section 10(b) and SEC Rule 10b-5. Matrixx argues that to be material information, adverse-event reports must provide statistically significant evidence of a causal relationship between drug use and adverse events.¹⁵³ Siracusano maintains that determining whether information is material requires a factual inquiry that would be barred in many cases by the imposition of the statistical significance standard.¹⁵⁴ The First, Second, and Third Circuit Courts of Appeal have applied the statistical significance standard to this materiality determination, requiring adverse-event reports to demonstrate statistically significant evidence of a nonrandom link between drug

150. *Id.* at 37, 52.

151. *See id.* at 51–52.

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

153. Brief for Petitioners, *supra* note 1, at 15–16.

154. Brief for Respondents, *supra* note 3, at 21–22.

use and adverse events.¹⁵⁵ The Ninth Circuit, on the other hand, rejected this standard.¹⁵⁶ The Supreme Court most likely will resolve this split by affirming the Ninth Circuit's holding and rejecting the statistical significance standard as a departure from the *Basic* Court's emphasis on a comprehensive factual determination.

155. *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 47 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998); *Oran*, 226 F.3d at 284.

156. *Matrixx Initiatives, Inc. v. Siracusano (Matrixx II)*, 585 F.3d 1167, 1179–80 (9th Cir. 2009).