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Supreme Court Agrees to Hear *Matrixx*, Concerning Materiality & Adverse Events

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Recently, the Supreme Court granted certiorari in *Matrixx, Inc. v. Siracusano*—thereby agreeing to consider important questions relating to the pleading of materiality, and potentially to the pleading of scienter, in securities-fraud class actions.[1]

In *Matrixx*, investors brought a securities-fraud class action against Matrixx, Inc., a pharmaceutical company, and three of its executives. Investors claimed that the defendants had failed to disclose certain adverse event reports about the company's nasal spray/gel Zicam in connection with the plaintiffs' purchase of Matrixx stock.[2] The U.S. Court of Appeals for the Ninth Circuit held that the plaintiffs were not required to plead that the adverse event reports at issue were "statistically significant" in order to state a claim under 10b-5. In so holding, the Ninth Circuit reversed the district court, which had dismissed the plaintiffs' complaint for its failure to plead statistical significance.[3] The Ninth Circuit's holding also broke with prior case law from the U.S. Courts of Appeals for the First, Second, and Third Circuits. The circuit split seems to arise from variances in the usage and, perhaps, from the misuse of the term "statistical significance."

The Supreme Court will now address this circuit split by answering the following question presented: "Whether a plaintiff can state a claim under [10b-5] based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant."[4]

Background

Omitted facts must be material for the omissions to be actionable. Moreover, as

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the Supreme Court explained in *TSC Industries, Inc. v. Northway, Inc.*, quoted in *Basic Inc. v. Levinson*, "to fulfill the materiality requirement, 'there must be 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.'"[5] The core question at issue in *Matrixx* is whether adverse events that were not statistically significant might still be material, such that a securities-fraud complaint could still be based on their nondisclosure. Put another way, the case asks the following question: Are statistically significant adverse events the only kind of adverse events that are material, and thus the only kind that can form the basis for a securities-fraud claim?

The adverse events in *Matrixx* related to a connection between Zicam and anosmia, a loss of the sense of smell that can be permanent. During the class period, October 22, 2003, to February 6, 2004, defendants allegedly knew the following about said connection:

- In December 1999, Dr. Alan Hirsch, the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., called Matrixx customer service to report that at least one of his patients contracted anosmia after using Zicam.
- In September 2002, defendant Timothy Clarot, Matrixx's Vice President of Research and Development, called Miriam Linschoten, Ph.D., of the University of Colorado Health Sciences Center, because a patient whom Dr. Linschoten had treated for anosmia after using Zicam had complained to Matrixx. Clarot disclosed to Dr. Linschoten that Matrixx had received similar complaints as early as 1999.
- A September 20, 2003, collaborative presentation by medical researchers at the University of Colorado School of Medicine, Department of Otolaryngology, to the American Rhinologic Society identified 10 Zicam users who suffered from anosmia ("University of Colorado Study"). Previously, on September 12, 2003, Matrixx informed the University that it did not have Matrixx's permission to use its company name or product trademarks in the University of Colorado Study.
- Between October 14, 2003, and January 23, 2004, four lawsuits were filed against Matrixx regarding a connection between Zicam and anosmia. During the class period, these lawsuits included a total of nine individual plaintiffs.[6]

Yet, during the class period, Matrixx did not disclose any of this information. Instead, Matrixx made numerous statements declaring Zicam safe and even described the evidence of a connection between it and anosmia as "unfounded and misleading."[7] When subsequent news reports disclosed additional links between Zicam and anosmia, as well as disclosing pending lawsuits and the threat of additional ones, Matrixx's share price fell. The plaintiffs then filed suit, contending that Matrixx's alleged misstatements and non-disclosure of the adverse events violated 10b-5.

The Arizona district court judge who was assigned to the case, Judge Mary H. Murguia, dismissed the plaintiffs' complaint. Relying on a line of cases from the courts of appeals, particularly the Second Circuit's decision in *In re Carter-Wallace, Inc. Securities Litigation* (*Carter-Wallace I*),[8] the district court found that since the plaintiffs did not allege that the adverse events were statistically significant, the plaintiffs had failed to adequately plead materiality.[9] However, the Ninth Circuit reversed, holding that "the district court erred in relying on the statistical significance standard to conclude that [plaintiffs] failed adequately to allege materiality."[10] Judge Wallace Tashima, writing for the circuit panel, concluded that the decision as to whether the nondisclosed facts were material should have been made by the trier of fact.[11] The Ninth Circuit thereby created a circuit split with the First, Second, and Third Circuits, which the Supreme Court granted certiorari to address.

In short, the First, Second, and Third Circuits all held that when plaintiffs allege that a pharmaceutical company's nondisclosure of adverse events violates 10b-5, plaintiffs must plead that these events are statistically significant. The spe-

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cifics of those contrary decisions are as follows: The Second Circuit authored the seminal decision on the issue in *Carter-Wallace I*, which held that "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until 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."[12] The court reasoned that since the reports received during the class period were not statistically significant, plaintiffs had failed to properly plead materiality. It accordingly dismissed plaintiffs' claims. The Third Circuit, in *Oran v. Stafford*, a decision penned by then-Judge Samuel Alito, expressly adopted the *Carter-Wallace I* holding.[13] Finding that statistical significance had not been alleged, *Oran* held that the plaintiffs had failed to adequately plead that nondisclosed adverse events were material, and thus dismissed the claim.[14] The First Circuit, in *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, also dismissed a 10b-5 claim, in part, for failure to plead statistical significance.[15] However, *Biogen* did not dismiss the claim for the failure to allege materiality.[16] Instead, *Biogen* found that the failure to plead statistical significance was one of the reasons that the plaintiffs could not adequately plead scienter, also a prerequisite for stating a 10b-5 claim.[17]

The Ninth Circuit then broke from its sister circuits in *Matrixx*. Its decision was grounded in the Supreme Court's treatment of materiality. In particular, the Ninth Circuit quoted *Basic* in support of its conclusion that the determination of materiality is a "'fact-specific inquiry'" requiring "'delicate assessments'" that "'should ordinarily be left to the trier of fact.'"[18] The Ninth Circuit viewed an inflexible requirement of statistical significance as an example of the kind of bright-line rule regarding materiality that *Basic* had soundly rejected.[19] In *Basic*, the rejected bright-line test was that of "agreement-in-principle." This test determined the materiality of preliminary merger discussions based on a single occurrence: If discussions took place before merger partners reached agreement-in-principle—that is, agreement on a merger's price and structure—then those discussions were not material.[20] The Supreme Court rejected this approach. Similarly, the Ninth Circuit held that facts not alleged to be statistically significant could still be material.

Meaning of 'Statistical Significance'

Considering that the term "statistical significance" looms so large, it is surprising that the courts of appeals decisions discussed above spend so little time contemplating what it actually means. In fact, the term has a precise meaning. It "is a technical term that concerns only whether an observed relationship is real or is the product of chance variation or the effect of an intervening variable."[21] Statistical significance "means that an observed difference cannot be attributed to chance alone, that something besides random error is afoot."[22] Yet courts have largely neglected the technical and scientific underpinnings of the concept in favor of a more subjective standard, which in practice has morphed into a proxy for the materiality of pharmaceutical adverse event reports. Courts have described that subjective standard in numerous ways—for example, as requiring that the reports be scientifically meaningful, be reliable, represent a consensus, encompass a certain number of events, show causation, be "not random," establish a serious health risk, or affect the product's commercial viability or the company's future earnings.[23] These numerous criteria seem to be no more than an attempt to provide guidelines on determining materiality in the unique context of the pharmaceutical industry. Since statistical significance is being used as a proxy for materiality, courts have thus circularly held that the key inquiry in determining whether adverse events are material is whether they are material.

Therefore, the circuit split created by *Matrixx* could simply represent two different understandings of statistical significance: a technical test and a judicial proxy test. The proxy test is not necessarily wrong. A court could rightly conclude, as the Second Circuit did in *Carter-Wallace I*, that nondisclosed facts were not material because they failed to: (1) report a significant number of deaths; (2) represent significant evidence that

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deaths were caused by—rather than randomly associated with—the drug in question; and (3) indicate a significant threat to future earnings.[24] However, the Supreme Court should call a spade a spade: The phrase "statistical significance" has a precise meaning. Having scientists and expert witnesses use one meaning, while courts employ a more subjective definition of the term, creates a discord that ultimately harms the investor, because it disrupts certainty as to the law's meaning and application, and can result in the dismissal of meritorious claims for securities fraud.

Another important distinction is that the precise meaning of statistical significance runs afoul of *Basic's* prohibition on bright-line rules, while a proxy meaning does not. In *Basic*, the Court spoke clearly: "Any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive."[25] Technical statistical significance is such an approach: It designates a certain percentage, defining the strength of causation, as being completely determinative as to the fact-specific finding of materiality. In contrast, proxy statistical significance is not a bright-line test, because it holistically captures several criteria that courts use to determine the materiality of adverse events.

In addition, an approach based on technical statistical significance suffers from another flaw as well: It is a subjective test over which scientists vigorously disagree. A recent case from Judge Laura Swain in the Southern District of New York, *In re Pfizer Inc. Securities Litigation*, dug into the meaning of "statistically significant" and came out at odds with *Carter-Wallace I*.[26] In *Pfizer*, on a motion to dismiss, plaintiffs and defendants disagreed over whether certain adverse events were statistically significant. They cited differing scientific studies, which disagreed over details—such as the threshold percentage for statistical significance, and whether the adverse events should be broken into subgroups or examined in the aggregate. The court found that it could not choose which expert was correct, and declined to take judicial notice of the meaning of statistical significance.[27] The court explained that the proffered definitions of statistical significance were not admissible under the Federal Rules of Evidence because they were not "'generally known,'" nor were they "'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'"[28] Thus, the court, mindful that "materiality is a flexible, fact-based determination," concluded that "statistical significance is a question of fact."[29] The Ninth Circuit in *Matrixx* quoted the above holding from *Pfizer* in explaining its reversal of the district court.[30]

Pfizer's comprehensive treatment of statistical significance also points to the difficulty of considering the issue at the pleading stage. If investors are forced to plead technical statistical significance, then they must procure an expert to reach this conclusion before even filing a 10b-5 lawsuit. This is an onerous requirement. Further, if investors can successfully plead technical statistical significance, defendants could respond with their own expert opinion disputing statistical significance—the scenario in *Pfizer*. Courts are loath to resolve dueling expert battles at the pleading stage. And there is substantial disagreement over technical statistical significance. It is represented by an equation which measures whether the evidence of causation meets a preset value (the *p-value*), which indicates that the causation has not occurred by chance. This *p-value* is entirely arbitrary, but 5% is often chosen, apparently out of convention.[31] Experts can come to different conclusions over whether adverse events are statistically significant by simply disagreeing over the *p-value*.[32] Finally, statistical significance differs from practical or legal significance. The legal question of what is more likely than not is very different from the question of what is statistically significant—an inquiry that often distinguishes narrow differences in degree of probability.[33]

Courts' adopting a proxy test for statistical significance is also damaging to the investor, because courts can thereby dismiss even claims that plead material adverse events. Statistical significance still has a precise meaning. Therefore, investors need to retain an expert to examine the adverse events at issue, pursuant to a precise meaning of statistical significance, before they can plead it. However, the *Matrixx* plaintiffs never pled sta-

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tistical significance even though, intuitively, the adverse events seem to constitute enough factual matter to suggest that they are material.[34] It would be dubious to conclude that, as a matter of law, no reasonable investor would believe that the adverse events that had been reported, but not disclosed, had significantly altered the total mix of available information on Zicam. Notably, the University of Colorado Study stands out as a particularly compelling example of materiality. Even though plaintiffs did not have an expert conclude that the Zicam-anosmia link met a certain *p-value*, a reasonable investor could certainly view the adverse events at issue as meaningful, reliable, establishing a serious health risk, impacting future earnings, and therefore material.

Conclusion

In sum, holding any particular formulation of statistical significance out as the sine qua non of materiality seems to shortchange the concept of materiality. Statistical significance should be but one of several characteristics that determine the materiality of adverse event reports. For example, materiality could be influenced by direct observations of adverse events, even if they are not statistically significant. Likewise, particularly egregious reactions to a pharmaceutical could alter the total mix of information even if these reactions were not sufficiently numerous to be statistically significant. Furthermore, one can assume that there is a numerical threshold at which adverse event reports become uncontroversially statistically significant.[35] Since a company's share price is a function of that company's anticipated future earnings, an adverse event which results in a drug being, say, only one adverse event short of uncontroversial statistical significance could certainly be material to an average investor. If a court were to hold that, as a matter of law, such an adverse event was not material because the threshold had not been reached, then it would be engaging in the sort-of bright-line thinking that *Basic* rejected, and that is incompatible with the delicate assessments that materiality requires.

Matrixx, in its certiorari briefing, criticized the Ninth Circuit's decision as hugely disruptive, potentially forcing pharmaceutical companies to disclose every adverse event that occurs. This kind of comprehensive adverse event disclosure would, according to the defendants, deter consumers from using beneficial, life-saving drugs and would overwhelm investors with meaningless information, rendering them unable to make informed investment decisions.[36]

Yet the Supreme Court rejected these types of arguments in *Basic*. It emphasized that disclosure, not a paternalistic withholding of information, was the thrust of 10b-5, and cautioned against attributing a child-like simplicity to the average investor.[37] Mindful of this average investor, we believe that it is unwise to use statistical significance—be it proxy or precise—as the sole determinant of what he or she deems material.

NOTES

1. Order Granting Certiorari in *Matrixx v. Siracusano* (09-1156), June 14, 2010, *available at* 2010 WL 1180367 (U.S. 2010) and http://www.supremecourt.gov/qp/09-01156qp.pdf.
2. Plaintiffs allege that defendants violated § 10(b) of the Securities Exchange Act, 15 U.S.C.A. § 78j(b), and SEC Rule 10b-5 (collectively, "10b-5").
3. *Siracusano v. Matrixx, Inc.*, 585 F.3d 1167, Fed. Sec. L. Rep. (CCH) P 95386 (9th Cir. 2009), cert. granted, 2010 WL 1180367 (U.S. 2010), rev'g *Siracusano v. Matrixx, Inc.*, Fed. Sec. L. Rep. (CCH) P 93733, 2005 WL 3970117 (D. Ariz. 2005), judgment rev'd, 585 F.3d 1167, Fed. Sec. L. Rep. (CCH) P 95386 (9th Cir. 2009), cert. granted, 2010 WL 1180367 (U.S. 2010).
4. *Matrixx* Certiorari Order, *supra* note 1.
5. *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449, 96 S. Ct. 2126, 48 L. Ed. 2d 757, Fed. Sec. L. Rep. (CCH) P 95615 (1976), quoted in *Basic Inc. v. Levinson,* 485 U.S. 224, 231, 108 S. Ct. 978, 99 L. Ed. 2d 194, Fed. Sec. L. Rep. (CCH) P 93645, 24 Fed. R. Evid. Serv. 961, 10 Fed. R. Serv. 3d 308 (1988).
6. *Matrixx*, 585 F.3d at 1170-1171, 1179.
7. *Matrixx*, 585 F.3d at 1173.
8. *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, Fed. Sec. L. Rep. (CCH) P 90241 (2d Cir. 1998)(*Carter-Wallace I*) (Winter, C.J.).
9. *Matrixx*, 2005 WL 3970117 at *7.
10. *Matrixx*, 585 F.3d at 1178.
11. *Matrixx*, 585 F.3d at 1179.
12. *Carter-Wallace I*, 150 F.3d at 157.

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13. *Oran v. Stafford*, 226 F.3d 275, 284, Fed. Sec. L. Rep. (CCH) P 91205, 55 Fed. R. Evid. Serv. 872 (3d Cir. 2000) (quoting *Carter-Wallace I*).
14. *Oran*, 226 F.3d at 284.
15. *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008) (Lynch, C.J.).
16. The underlying district court opinion had found that the omitted facts were material, and the Court of Appeals did not address the materiality issue, assuming *arguendo* that materiality had been pled. *Biogen*, 537 F.3d at 44. It may therefore be more accurate to say that *Matrixx* only pits the Second and Third Circuits against the Ninth.
17. *Biogen*, 537 F.3d at 50-53.
18. *Matrixx*, 585 F.3d at 1178 (quoting *Basic,* 485 U.S. at 236, 240; *S.E.C. v. Phan*, 500 F.3d 895, 908, Fed. Sec. L. Rep. (CCH) P 94377 (9th Cir. 2007)).
19. *Matrixx*, 585 F.3d at 1178.
20. *Basic,* 485 U.S. at 236.
21. Melvin Aron Eisenberg, *Bad Arguments in Corporate Law*, 78 Geo. L.J. 1551, 1555 (1990), *quoted in* Brief of Respondents James Siracusano and NECA-IBEW Pension Fund in Opposition to Petition for Writ of Certiorari at 18, *Matrixx* (No. 09-1156).
22. Jack F. Williams, *Distrust: The Rhetoric and Reality of Means-Testing*, 7 Am. Bankr. Inst. L. Rev. 105, 131 n.105 (1999), *quoted in* Brief of the Respondents, *supra* note 21, at 18.
23. *Carter-Wallace I*, 150 F.3d at 157; *Oran*, 226 F.3d at 284-286; *Biogen,* 537 F.3d at 58; *Matrixx*, 2005 WL 3970117 at *5-6.
24. *Carter-Wallace I*, 150 F.3d at 157.
25. *Basic,* 485 U.S. at 236.
26. *In re Pfizer Inc. Securities Litigation*, 584 F. Supp. 2d 621 (S.D. N.Y. 2008).
27. *Pfizer*, 584 F. Supp. 2d at 634.
28. *Pfizer* (quoting Fed. R Evid. 201(b)).
29. *Pfizer*, 584 F. Supp. 2d at 635-636 (quoting *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 162, Fed. Sec. L. Rep. (CCH) P 91210 (2d Cir. 2000)).
30. *Matrixx*, 585 F.3d at 1179.
31. *See Pfizer*, 584 F. Supp. 2d at 634 ("It is one thing to take notice of the fact that an author has written that 5% is the threshold for statistical significance. It is quite another thing entirely to use that 5% figure as a basis for rejecting the significance of complicated medical studies."); Stephen Stigler, *Fisher and the 5% Level*, 21 CHANCE 4 (Dec. 2008), *available at* http://www.springerlink.com/content/p546581236kw3g67/.
32. *Pfizer*, 584 F. Supp. 2d at 634-635.
33. Richard Lempert, Symposium on Law and Economics, *Statistics in the Courtroom: Building on Rubinfeld*, 85 Colum. L. Rev. 1098, 1099 (1985), *quoted in* Brief of the Respondents, *supra* note 21, at 19.
34. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556, 127 S. Ct. 1955, 167 L. Ed. 2d 929, 2007-1 Trade Cas. (CCH) ¶ 75709, 68 Fed. R. Serv. 3d 661 (2007).
35. *See In re Carter-Wallace, Inc., Securities Litigation*, 220 F.3d 36, 42 (2d Cir. 2000) (*Carter-Wallace II*) (Meskill, J.) (finding that four more adverse event reports occurring after class period ended established link between drug and adverse event).
36. Brief of Petitioners Matrixx Inc., *et al*. for a Writ of Certiorari at 2-3, *Matrixx* (No. 09-1156).
37. *Basic,* 485 U.S. at 235-236.

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