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The Supreme Court Grapples with the Concerns of Pharmaceutical Companies & Their Investors at Oral Argument in *Matrixx*

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On January 10, the Supreme Court heard oral argument in *Matrixx Initiatives, Inc. v. Siracusano*, addressing the following question presented: "Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant."[1]

In *Matrixx*, investors brought a securities-fraud class action against Matrixx Initiatives, Inc., a pharmaceutical company, and three Matrixx executives. Plaintiffs claimed that the defendants had failed to disclose 23 adverse event reports about the company's nasal spray/gel Zicam in connection with the purchase of Matrixx stock. The reports related to a connection between Zicam and anosmia, the loss of an individual's sense of smell. [For more on the *Matrixx* case, see the July/August 2010 issue of *Securities Litigation Report*, vol. 7, no. 7.]

The U.S. Court of Appeals for the Ninth Circuit held, on a motion to dismiss, that investors did not have to plead that adverse events reports not disclosed by Matrixx were statistically significant in order to satisfy the materiality requirement of Rule 10b-5.[2] *Statistical significance* "means that an observed difference cannot be attributed to chance alone, that something besides random error is afoot."[3] It "is a technical term that concerns only whether an observed relationship is real… ."[4] *Materiality* is a prerequisite to establishing a violation of Rule 10b-5. The Supreme Court has explained that, "to fulfill the materiality requirement, 'there must be a substantial likelihood that the disclosure of the omitted fact would

CONTINUED ON PAGE 3

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have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'"[5]

Even though it can be difficult to predict outcomes based on an oral argument, the mainstream media and most commentators believe that the Court will side with the plaintiff-investors by affirming the question presented.[6] Matrixx's attorney acknowledged that there are limited circumstances where a Rule 10b-5 claim can be pled absent statistically significant evidence—where causation is found even though statistical significance is not satisfied.[7] Justice Sonia Sotomayor saw this concession as evidence of Matrixx having answered the question presented in the affirmative.[8] Justice Stephen Breyer was even more explicit, responding to Matrixx's lawyer's argument that investors must plead statistical significance with, "[o]h, no, it can't be," and later, "[s]o I can't see how we can say this statistical evidence always works or always doesn't work."[9]

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The Court's questions focused on indicia of materiality besides statistical significance, such as the reliability, volume, seriousness, history, and other characteristics of adverse events. For example, Justice Elena Kagan presented a thoughtful hypothetical: a company makes only one product, a contact lens solution sold to many hundreds of thousands of individuals, where 10 use the product and go blind, including three who borrow one lens from a friend and go blind only in that one eye. While the number of adverse events would not be enough to satisfy statistical significance, Justice Kagan would have responded by not using the product and selling whatever stock she had in its manufacturer. In Justice Kagan's hypothetical, this non-statistically significant information was material.[10] The Court seemed to see statistical significance as a bright-line rule, and, pursuant to *Basic Inc. v. Levinson*, a bright-line rule cannot be the sole determinant of materiality.[11] In *Basic*, the Court rejected a similarly inflexible rule for determining materiality because materiality is a "fact-specific inquiry" requiring "delicate assessments" that "should ordinarily be left to the trier of fact."[12]

Having largely answered the question presented, the oral argument can be understood as the Court's grappling with the question of when adverse event reports are material. Failure to provide clear guidance could be burdensome to both drug companies and individuals who invest in them and/or use their products. To address this, the Court zeroed in on whether a drug company is obligated to disclose adverse event reports that lack any credibility at all. And here the justices' questions even drew laughter from the audience as they asked about increasingly noncredible, and humorous, adverse event reports.

Psychics & Satan

Early in the oral argument, Chief Justice John G. Roberts told Matrixx's attorney, "You 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 20%, it seems to me that's material."[13] Justice Anthony Kennedy then asked Matrixx's attorney whether there would be a duty to disclose an event stipulated as irrational and baseless but having an adverse impact on the market.[14] Matrixx's attorney answered that there would be no such obligation. He drew an ex ante/hindsight distinction, arguing that even if a company's share price fell as a result of a baseless report that, ex ante, the company could not be expected to know of the impact on its share price and therefore would have no duty to disclose. Further, he argued that failure to disclose would not evidence *scienter* (knowledgeable or intentional wrongdoing, which is another Rule 10b-5 prerequisite). However, Justice Antonin Scalia, suggested that, a company's failure to disclose an adverse event, regardless of its credibility,

that it knew at the time would have an impact on its share price would constitute *scienter*.[15]

The investors' attorney disagreed with Matrixx's arguments, positing a hypothetical where if a "large body of followers" irrationally believed that a product had "satanic influences," a reasonable investor would want a company to disclose this information if it affected stock price.[16] The Chief Justice responded that this would offer no protection to a drug company—that an investor could simply plead securities fraud by alleging that had a drug company disclosed a product's "satanic susceptibility" that company's share price would decrease.[17] This observation is in line with the Court's recent direction in *Twombly* and *Iqbal*, cases that tighten the pleading standards for plaintiffs to survive motions to dismiss.[18]

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One of the reasons Matrixx argued for a statistical significance standard is that it clarifies when it is not obligated to disclose adverse event reports. However, the Supreme Court has emphasized that companies' disclosure, not a paternalistic withholding of information, is the thrust of Rule 10b-5. The Court has cautioned against attributing a child-like simplicity to the average investor.[19] Yet, the Court is well aware that drug companies receive a steady humdrum of adverse reports about their products—what Justice Breyer repeatedly referred to as "background noise"—so that these companies need guidance on when they must disclose.[20] Without guidance, drug companies would likely defend themselves from a barrage of lawsuits by disclosing everything.

If drug companies disclose all "background noise," it could overwhelm investors with meaningless information and even deter consumers from using beneficial, life-saving drugs. Chief Justice Roberts made clear the importance of the average investor's interests. Early on, he advised Matrixx's attorney, "[Y]ou're talking about who is right or wrong about the connection between Matrixx and anosmia. But that's not the question. I'm an investor in Matrixx; I worry whether my stock price is going to go down."[21] Even if adverse event reports are baseless and even if only unreasonable investors respond to them, the Chief Justice noted that a reasonable investor would still be worried if thousands of unreasonable investors respond to a baseless report by selling their Matrixx stock.[22] That affects share price. Justice Scalia took issue with the Chief Justice's musings by opining that it is "ridiculous" to expect the "reasonable investor [to] take[] account of the irrationality."[23]

A New Test?

So, assuming the Court does not adopt a bright-line test to determine whether adverse event reports must be disclosed, what are drug companies and their investors to do with all this noise? And how can district courts determine whether investors have adequately pled a company's failure to disclose adverse event reports under Rule 10b-5? The insights offered by Pratik Shah, assistant to the Solicitor General, who argued on behalf of plaintiff-investors, are revealing.

First, Shah reminded the Court that under Rule 10b-5, there is no duty to disclose unless a statement made by the company would be rendered misleading by its omitting a material fact.[24] So if Matrixx had not made optimistic projections of future earnings, it would have had no duty to disclose regardless of the materiality of adverse events. Second, Shah pointed the Court to a useful blueprint to craft an opinion adopting a fact-intensive totality of the circumstances test to determine materiality of adverse events. Such a test seems to comport with *Basic* and the justices' sentiments expressed at oral argument. The blueprint was suggested by the Securities and Exchange Commission, to which the Court tra-

ditionally accords "due deference" on securities matters.[25]

[I]f Matrixx had not made optimistic projections of future earnings, it would have had no duty to disclose regardless of the materiality of adverse events.

Shah cited the government's brief, which lists the following factors endorsed by the SEC:

- an adverse event report's source, rate, and severity;
- a drug's potential benefit;
- the availability of alternate therapies;
- whether the drug is new and has received approval from the U.S. Food and Drug Administration;
- the plausibility of a causal link between the drug and the adverse event; and
- the importance of the drug to the company's financial outlook.[26]

When the Supreme Court releases its opinion in *Matrixx*, these factors could very well constitute the Court's new guidelines for pharmaceutical companies and their investors to determine what to do with adverse events reports.

NOTES

1. Order Granting Certiorari in *Matrixx Initiatives, Inc. v. Siracusano* (09-1156), 2010 WL 1180367 (S. Ct. June 14, 2010). Section 10(b) of the Securities Exchange Act, 15 U.S.C.A. § 78j(b), and SEC Rule 10b-5 are collectively referred herein to as "Rule 10b-5."
2. *Matrixx,* 585 F.3d 1167, Fed. Sec. L. Rep. (CCH) P 95386 (9th Cir. 2009), cert. granted, 130 S. Ct. 3411, 177 L. Ed. 2d 323 (2010) *reversing Siracusano v. Matrixx Initiatives, 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, 130 S. Ct. 3411, 177 L. Ed. 2d 323 (2010).
3. Jack F. Williams, *Distrust: The Rhetoric and Reality of Means-Testing,* 7 Am. Bankr. Inst. L. Rev. 105, 131 n.105 (1999).
4. Melvin Aron Eisenberg, *Bad Arguments in Corporate Law*, 78 Geo. L.J. 1551, 1555 (1990).
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. *See, e.g.*, Adam Liptick, *Justices Take Up Zicam Case, Questioning Maker on Disclosure to Investors*, N.Y. Times, Jan. 10, 2011, at B3, *available at* http://www.nytimes.com/2011/01/11/business/11bizcourt.html?_r=1 ("Matrixx did not appear to get much traction for its main argument—that a failure to disclose reports of adverse effects should give rise to securities fraud liability only if the reports were collectively statistically significant."); J. Robert Brown Jr., *The Supreme Court in Matrixx: Materiality and Satanic Susceptibility*, The Race to the Bottom, January 18, 2011, http://www.theracetothebottom.org/home/the-supreme-court-in-matrixx-materiality-and-satanic-suscept.html ("While it is hard to predict the outcome of a case from oral argument, this one seems straightforward. Respondents will win and the Supreme Court will reject the 'statistical significance' test, reaffirming the traditional *Northway/Basic* analysis.").
7. Transcript of Oral Argument (official, subject to final review) at 5:22-6:2, *Matrixx*, No. 09-1156, 2011 WL 65028 (S. Ct. Jan. 10, 2011).
8. *Matrixx* transcript at 24:25-25:1.
9. *Matrixx* transcript at 20:25, 21:9-10.
10. *Matrixx* transcript at 17:20-18:10, 18:16-21.
11. *Basic Inc. v. Levinson*, 485 U.S. 224, 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).
12. *Matrixx*, 585 F.3d at 1178 (9th Cir.) (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)).
13. *Matrixx* transcript at 8:2-6.
14. *Matrixx* transcript at 9:3-7.
15. *Matrixx* transcript at 43:11-22.
16. *Matrixx* transcript at 37:4-5.
17. *Matrixx* transcript at 38:17. Not to be outdone, Justice Scalia later interrupted Pratik Shah, assistant to the Solicitor General, within seconds after his taking the podium, to ask, "Mr. Shah,

what do you think about Satan?" *Matrixx* transcript at 46:10-11.

18. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929, 2007-1 Trade Cas. (CCH) P 75709, 68 Fed. R. Serv. 3d 661 (2007); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 173 L. Ed. 2d 868, 2009-2 Trade Cas. (CCH) P 76785, 73 Fed. R. Serv. 3d 837 (2009).
19. *Basic*, 485 U.S. at 235-236.
20. *See, e.g.*, *Matrixx* transcript at 20:21, 21:21, 22:9, 18.
21. *Matrixx* transcript at 7:24-8.2.
22. *Matrixx* transcript at16:10-13.
23. *Matrixx* transcript at 39:11, 15-16.
24. *Matrixx* transcript at 48:17-23.
25. *Basic*, 485 U.S. at 239 n.16 (citing *TSC v. Northway*, 426 U.S. at 449 n.10).
26. *Matrixx* transcript at 52:18-21 (citing Brief for the United States as Amicus Curiae Supporting Respondents at 28-29, *Matrixx,* (No. 09-1156)).