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Supreme Court Hears Oral Argument in Securities Class Action on Materiality of Adverse Events

The Supreme Court Monday heard oral argument in *Matrixx Initiatives Inc., et al.* v. *Siracusano*, a putative securities class action involving the manufacturer of Zicam Cold Remedy. The case presents the question of whether a company's non-disclosure of adverse event reports that are not statistically significant can subject it to liability under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5. It has potentially far-reaching implications for pharmaceutical companies' duty to disclose reports of adverse events to investors and has attracted significant attention from stakeholders in government, the pharmaceutical and biotechnology industries, and the investment community.

Background. The *Matrixx* case arises out of allegations that Zicam Cold Remedy causes users to lose their sense of smell. Individuals and institutions that purchased securities of Matrixx between October 22, 2003 and February 6, 2004 brought a putative class action alleging that Matrixx failed to disclose material information regarding Zicam – namely, that Matrixx had received adverse event reports between 1999 and 2004 purporting to link loss of smell with Zicam use.

Proceedings below. The United States District Court for the District of Arizona dismissed the class action complaint for failure to state a claim, finding that the plaintiffs had not alleged that the adverse events were statistically significant, and therefore that the adverse events failed to meet the standard for materiality.[1] The Ninth Circuit reversed and remanded, rejecting a bright-line "statistical significance" test for materiality. Citing the Supreme Court's holding in *Basic Inc.* v. *Levinson*, 485 U.S. 224 (1988), the Ninth Circuit reasoned that the materiality determination in securities fraud cases instead requires a fact-specific inquiry and assessment of the inferences a reasonable shareholder might draw from a given set of facts. It concluded that the allegations in the complaint, construed in the light most favorable to plaintiffs, contained information that a reasonable investor would have considered significant, and therefore stated a claim sufficient to survive a motion to dismiss.

Matrixx's petition. In support of its petition for *certiorari*, Matrixx argued that, in rejecting the statistical significance test, the Ninth Circuit has created a split with the only other circuits that have addressed this question – the First, Second, and Third Circuits – that will alter the legal landscape and facilitate forum-shopping. Relatedly, it argued that the Ninth Circuit standard would dramatically expand the burdens on pharmaceutical and biotechnology companies by requiring them to disclose information that is useless or likely to confuse consumers, while at the same time subjecting them to excessive and frivolous litigation.

[1] In a separate portion of the opinion, the district court also found that plaintiffs' allegations were insufficient to establish scienter. Because the dispute about the materiality standard is of more general applicability, we focus on that portion of the case for purposes of this alert.

Respondents' opposition. In opposing the petition, the shareholder plaintiffs argued that the Ninth Circuit properly rejected the statistical significance test as the standard for materiality, contending that whether a correlation is statistically significant is a different inquiry than whether it is practically or legally significant. They also disputed that there is a circuit split on the issue of materiality, arguing that Matrixx's position to the contrary relies on a misconstruction of the law.

Amicus curiae. The case has unsurprisingly attracted attention from various stakeholders, reflected in the numerous *amicus curiae* filed before the Court. For instance, among others, Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO) submitted a brief in support of *Matrixx's* position. PhRMA and BIO argued that, because statistically insignificant adverse event reports permit no reasonable inference of causation, the reports would not reasonably affect a pharmaceutical manufacturer's earnings and could not be considered material. They also argued that the Ninth Circuit standard would lead to overdisclosure of adverse event reports and investor confusion and stock fluctuation, all of which would harm manufacturers, their investors, consumers and patients.

Other *amici*, including the U.S. Government, sided with the class plaintiffs. The United States argued that a bright-line rule based on statistical significance conflicts with *Basic Inc.* v. *Levinson* because (1) evidence that is not statistically significant can nevertheless suggest a causal link between a drug and an adverse effect; and (2) a reasonable investor may consider information suggesting an adverse drug effect important even if it does not prove that the drug causes the effect.

Oral arguments. Questioning by the Justices reflected skepticism about using statistical significance as a bright-line rule for the materiality of adverse events in drug cases. All of the justices except for Justice Thomas questioned the lawyers for both sides. The questions directed at counsel for Matrixx included hypotheticals seeking to understand whether there were facts about which a reasonable investor would be concerned (and thus were material) – even if they were not statistically significant or necessarily scientifically meaningful. Justice Ginsburg was the most active questioner of Matrixx.

In questioning counsel for Siracusano, the justices sought to understand, among other things, whether scientific information had to be credible and valid in order to qualify as material, or whether, in the words of Justice Roberts, information or theories that are "completely irrational" nonetheless had to be disclosed, if they could be reasonably expected to affect the stock price. He was the most active questioner of Siracusano.

Counsel also argued on behalf of the United States as *amicus curiae*, in support of Siracusano, asserting that the SEC was entitled to "significant deference" in opposing the bright-line statistical significance standard for materiality.

Conclusion. The Supreme Court is expected to rule on the case in June 2011. If it rejects the bright-line statistical significance standard for materiality, pharmaceutical and biotechnology companies will likely find themselves subject to more onerous disclosure requirements – and more class action lawsuits, as well.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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