Client Alert.

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United States Supreme Court Skeptical of Requiring Statistical Significance as the Test to Determine Materiality in Securities Fraud Cases

By Erik J. Olson and Stefan J. Szpajda

On Monday, January 10, 2011, the Supreme Court heard arguments in *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156. The Court previously granted certiorari in the case to decide: "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." To see more information on the underlying suit and more background on the case, view our prior client alert here.

Materiality and scienter, which are the primary legal issues in dispute in *Matrixx*, are two key elements of a securities fraud claim under section 10(b) of the Securities Exchange Act of 1934. The defendants argued that anecdotal information about reports of side effects or other adverse reactions are not meaningful to scientists and medical professionals and thus, their disclosure will not provide accurate information on the performance of a drug or device. Consequently, withholding information about adverse events cannot be misleading unless plaintiffs establish a statistically significant relationship between the adverse events and use of the drug or device. Defendants asked the United States Supreme Court to adopt this bright-line rule, consistent with the practices of the First, Second, and Third Circuit Courts of Appeal.

The plaintiffs countered that materiality is a contextual, fact-intensive inquiry. No bright-line rules or specific standard should apply. Rather, plaintiffs argued in favor of the use of a general test that is used to evaluate whether any omission is material — whether the omitted fact would have "significantly altered the 'total mix' of information . . . available" in the mind of the reasonable investor. *TSC Indus., Inc. v. Northway, Inc*., 426 U.S. 438, 449 (1976). Statistical significance may be relevant to the inquiry, but each case should be evaluated based on a review of all the evidence. This view was previously adopted by the Ninth Circuit Court of Appeals, and it was favored by the United States, which filed a brief in favor of plaintiffs on behalf of both the Securities & Exchange Commission and the Food & Drug Administration.

Questioning during yesterday argument suggests that a majority of the Justices are likely to favor the plaintiffs' position and reject the use of a specific bright-line rule. to be applied to disclosures by life sciences companies. No Justice appeared to champion the defendant's position.

The Justices, however, debated at several points how to identify clear principles by which to make a determination whether information is material. Despite an emphasis on the *reasonable* investor in Supreme Court precedent (see *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Tellabs Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308 (2007)), some Justices asked whether irrational concerns or false information about a drug or company might nonetheless be material if it was likely to change an investor's willingness to buy or sell a stock. Thus, in a market where even unsupported rumors or connections between a drug and potentially serious adverse events might affect a stock's price, how much negative

information must securities' issuers disclose? No one appeared satisfied with either side's answers to this question. Nor did the Court appear satisfied with the parties' answers regarding how to weigh the credibility of information that is withheld or how credible information must be before it needs to be disclosed in connection with a company's other statements.

What does this mean for public life sciences companies? First, companies should not rely exclusively on the lack of a statistically significant connection between adverse events and their product as their basis to decide when and how to qualify their otherwise positive statements about a product. Second, companies should consider whether to revise their disclosure procedures to account for the context-dependent nature of the likely future inquiry. Third, companies should focus carefully on the accuracy of what they do say. As Justice Ginsburg and the attorney arguing on behalf of the United States pointed out, the duty imposed by section 10(b) is a duty not to mislead. Thus, what must be disclosed depends in major part on what companies choose to say. As the Court said previously in *Basic v. Levinson*, "Silence is golden." However, when companies choose to speak, they must not mislead by half truths.

The Supreme Court is expected to issue a final decision in the case before the middle of June of this year.

For more information about *Matrixx*, securities litigation, or disclosure issues that apply to life sciences companies, contact Stephen Thau or Erik Olson.

Contact:

Erik J. Olson
(650) 813-5825
ejolson@mofo.com

Stephen B. Thau
(650) 813-5640
sthau@mofo.com

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