Client Alert.

March 22, 2011

In *Matrixx Initiatives, Inc. v. Siracusano*, the United States Supreme Court Reaffirms That Materiality Depends on a Contextual Analysis of What a Defendant Says

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On Tuesday, March 22, 2011, the United States Supreme Court decided *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156. The Court concluded unanimously "that the materiality of adverse event reports cannot be reduced to a bright-line rule." (Slip Op. at 1-2.) To evaluate materiality, the Supreme Court returned to the rule previously announced in *Basic v. Levinson*, 485 U.S. 224 (1988). "In *Basic*, we held that this materiality requirement is satisfied when there is '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." (Slip Op. at 9-10) (quoting *Basic*, 485 U.S. at 231-32.) Thus, materiality will depend on the context in which a statement was made. This includes an evaluation of the connection between the company's actual statement and the quality and nature of the information about adverse events that is omitted.

The Court did not adopt the rule proposed by the defendants, which would have required that plaintiffs demonstrate that the omitted adverse events showed a statistically significant connection to a drug or medical device to state a claim. While the degree of statistical significance continues to be relevant to the analysis, this factor alone is not determinative, and courts can evaluate statistical significance and many other factors to determine whether omitted information causes a company's statement to be materially misleading within the meaning of the securities laws.

At the same time, the Supreme Court issued a strong reminder that securities fraud is about speech, not silence. The Court wrote:

> Moreover, it bears emphasis that § 10(b) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading. 17 CFR § 240.10b-5(b); *see also Basic*, 485 U.S. at 239, n. 17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5"). Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market.
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> (Slip Op. at 16).

Consistent with this position, the Supreme Court also emphasized that information on adverse events did not need to be routinely disclosed. "Application of *Basic's* 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events." (Slip Op. at 15) "[T]he mere existence of reports of adverse events -- which says nothing in and of itself about whether the drug is causing the adverse events -- will not satisfy this standard. Something more is needed but that something more is not limited to statistical significance and can come from 'the source, content, and context of the reports.'" (Slip Op. at 16). The determination whether to provide information on adverse events must be decided in context. Statistical significance will be one factor, but not the only factor, that must be considered when making the judgment.

After a discussion of the legal principles summarized above, the Court conducted its own evaluation of the context of Matrixx Initiatives' statements and omissions. The Court looked in detail at the facts asserted about the alleged connection between use of Zicam and loss of patients' sense of smell (anosmia), which was the side effect at issue in the case. In light of the scientific evidence, the scope of the company's own research, the importance of Zicam to the company, and the timing and content of the company's statements, the Court concluded that omitted information on reported cases of anosmia following use of Zicam were material in light of Matrixx Initiatives' public statements, particularly its statements that public reports that Zicam caused anosmia were "completely unfounded and misleading" and that "the safety and efficacy of [Zicam] . . . have been well established." (*See* Slip Op. at 17-19). The Court went on to conclude that the facts alleged in the complaint were sufficient to satisfy the pleading requirements for demonstrating scienter in the present case.

Life sciences companies and other public companies can learn at least two lessons from the decision. First and foremost, be careful what you say. As the Court emphasized, the securities laws focus on false or misleading speech. "[C]ompanies can control what they have to disclose under these provisions by controlling what they say to the market." (Slip Op. at 16). Rash or categorical comments are far more likely to form the basis for a lawsuit than measured, careful statements about the facts.

Second, life sciences companies should consult carefully with lawyers regarding specific disclosures and policies and practices for disclosing adverse events. The strategy for each company will differ based on the products they produce, the status of FDA approval, the type and number of adverse event reports, whether the adverse events were statistically significant, and a variety of other factors. Companies are certain to receive an ongoing stream of adverse events reports from clinical trials or public use. Identifying in advance a strategy for when and how information about those adverse events might be disclosed is likely to help prevent future lawsuits. Moreover, adherence to such a strategy may both prevent future lawsuits and assist in the defense of them should they arise.

For additional background on the *Matrixx* case and on the underlying suit, view our prior client alerts here. Morrison & Foerster LLP previously filed an amicus brief on behalf of BayBio in connection with this case.

For more information about *Matrixx*, securities litigation, or disclosure issues that apply to life sciences companies, contact:

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