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On March 22, 2011, the United States Supreme Court issued an important decision for life sciences companies facing actual or potential securities litigation. The decision came in *Matrixx Initiatives, Inc. v. Siracusano*, a securities fraud class action challenging Zicam manufacturer Matrixx's failure to disclose adverse incident reports related to its over-the-counter cold remedy. The unanimous decision for plaintiffs reaffirms the long-standing test for materiality established in *Basic v. Levinson* (*Basic Inc. v. Levinson,* 485 U.S. 224 (1988)) and clarifies that, while adverse incident reports need not be disclosed in all cases, allegations of "statistical significance" are not necessary to establish materiality or scienter (fraudulent intent) at the pleading stage.

The case arises out of public statements by Matrixx in October 2003 that revenues from Zicam—which accounted for approximately 70 percent of its total revenues—were expected to be up by 50 to 80 percent for the year. Plaintiffs alleged that these statements were false and misleading because Matrixx was aware of dozens of adverse incident reports from consumers and medical experts, as well as industry papers and research studies, suggesting that Zicam causes loss of smell (anosmia). Moreover, while Matrixx warned in risk factors included in its filings with the SEC that product liability claims could have an adverse effect on the company, it failed to disclose that two Zicam users had already sued Matrixx for allegedly causing them to lose their sense of smell. Finally, when Matrixx stock dropped significantly following a Dow Jones report that the FDA was looking into such complaints, Matrixx issued a press release denying any connection between Zicam and anosmia and stating that "the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established." The stock bounced back following issuance of this press release. Matrixx later acknowledged that there was insufficient scientific evidence to confirm or refute any link between Zicam and anosmia, and that it had not performed any studies in this regard at the time it issued its release.

In its motion to dismiss, Matrixx argued that, absent allegations that the adverse incident reports established a statistically significant link between Zicam and anosmia, such reports were immaterial and could not establish any improper intent on the part of Matrixx and its executives. The district court agreed and dismissed the complaint, but the Ninth Circuit Court of Appeals reversed.

The Supreme Court affirmed the decision of the Ninth Circuit.

Of greatest significance, the Supreme Court rejected a "bright line" materiality test that had been adopted by some lower courts whereby adverse incidents involving a drug would be considered material only if they established a statistically significant correlation between the use of the drug and the adverse event. In rejecting such a test and reaffirming the fact-specific inquiry required under its earlier decisions, the Supreme Court held:

Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.… As a result, assessing the materiality of adverse event reports is a "fact-specific" inquiry, *Basic,* 485 U.S. at 236, that requires consideration of the source, context and content of the reports. This is not to say that statistical significance (or the lack thereof) is irrelevant—only that it is not dispositive of every case.

The Supreme Court cautioned, however, that the mere existence of adverse incident reports is insufficient to establish materiality because such reports say nothing in and of themselves about whether a drug is causing the adverse events. Rather, the relevant question continues to be whether a reasonable investor would view the nondisclosed information as significantly altering the total mix of information available about the company.

Applying this test, the Supreme Court concluded that allegations that Matrixx told the market that its revenues would dramatically rise and that Zicam was safe and effective at the same time that it knew of adverse incident reports and lawsuits indicating a significant risk to its leading revenue-generating product were sufficient to establish materiality at the pleading stage, even absent statistically significant data regarding the link between Zicam and anosmia.

Finally, the Supreme Court went out of its way to emphasize that neither section 10(b) nor Rule 10b-5 give rise to an affirmative duty of disclosure. "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." Thus, a company must disclose the existence of adverse incident reports—even if material—only

when necessary to render "statements made, in the light of the circumstances under which they were made, not misleading."

The decision will obviously have its greatest impact on life sciences companies. Once a drug is commercially launched, such companies will need to evaluate whether adverse incident or similar reports, even if not rising to a level of statistical significance, constitute material information. Among the factors noted by the Supreme Court that might influence such an analysis are the strength of the association between the drug and the adverse events, the temporal relationship between the drug and the event, the consistency of findings across available data sources, the seriousness of the events relative to the disease being treated, and the degree of benefit the drug provides compared to alternative sources. Other factors, such as the importance of the drug to the company's overall financial performance, would also be relevant.

The decision is likely to have a less significant impact in other industries as the Supreme Court essentially has reaffirmed its earlier decisions providing that materiality determinations require a "fact-specific" inquiry.

A copy of the decision can be accessed here.

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