

SUPREME COURT REJECTS THE 'STATISTICAL SIGNIFICANCE' REQUIREMENT TO PROVE MATERIALITY IN SECURITIES SUITS

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On March 22, 2011, in an unanimous opinion, the United States Supreme Court issued a decision in *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156, 563 U.S., slip op. (2011) on the materiality standard in securities fraud cases against pharmaceutical companies. The Court rejected Matrixx's contention that a securities fraud claim must allege that the company knew of a "statistically significant" number of adverse drug events for the company to have an obligation to make a disclosure to investors. Instead, the Court reaffirmed prior Supreme Court decisions and held that: (1) materiality is highly fact-specific; and (2) the test of whether information is material—and therefore must be disclosed—is based upon an objective standard of a "reasonable investor."

Going forward, the decision may significantly impair a company's ability to achieve early dismissals in litigation—before significant defense costs are incurred. In addition, in order to avoid such allegations in the future, companies might feel pressured to report many more adverse events to the public—even when the adverse events should not call the safety of the drug into question.

BACKGROUND

Matrixx, through its wholly owned subsidiary Zicam LLC, sells numerous over-the-counter cold remedy products, including a nasal spray and gel called Zicam Cold Remedy ("Zicam"). In 2004, plaintiffs filed a suit against Matrixx and certain of its directors and officers alleging that Matrixx violated the Exchange Act by failing to disclose material information—that Zicam caused some users to lose their sense of smell (a condition known as anosmia). Specifically, plaintiffs alleged that Matrixx was aware—but failed to disclose—"adverse event reports" (that is, reports by users of a drug that they experienced an adverse event after using the drug), including consumer complaints communicated to the company and product liability lawsuits filed against the company.

In 2005, the California District Court dismissed plaintiffs' claims, relying on authority from the Second and Third Circuits which provides that "adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe." The rationale behind this "statistical

significance" standard is that some adverse events can be expected to occur randomly, so until such adverse event reports show statistical significance, it is not reasonable to assume that such adverse events would be material to investors. The District Court, applying this standard, found that plaintiffs failed to present evidence of "a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publicly disclose [the adverse event reports] a material omission."

On appeal, the Ninth Circuit reversed the District Court's decision, finding that the lower court erred in relying on the "statistical significance" standard to conclude that plaintiffs failed to adequately allege materiality. Specifically, the Ninth Circuit found the statistical significance standard was at odds with the Supreme Court's prior rejection of "a bright line rule to determine materiality," which is a fact-specific inquiry which should "ordinarily be left to the trier of fact."

THE SUPREME COURT'S DECISION

The Supreme Court set the foundation by noting that there is no affirmative duty to disclose; disclosure is only required when the failure to disclose would constitute a misrepresentation. The Supreme Court agreed with the Ninth Circuit and rejected the lower court's reliance on the "statistical significance" standard. The Court rejected Matrixx's argument for a bright-line rule that "reports of adverse events associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish statistically significant risk that the product is in fact causing the events." The Court

stated that a bright-line rule would “artificially exclude evidence that would otherwise be considered to the trading of a reasonable investor.”

Further, the Court provided that Matrixx’s premise that “statistical significance is the only reliable indication of causation” is flawed. (Here, the Court uses the term “causation” to refer to the statistical conclusion that the drug is causing the adverse events. The Court is not discussing the causation element found in *Dura Pharmaceuticals v. Broud*, 544 U.S. 336 (2005)—the causation link that must be established by plaintiffs to prove a connection between the alleged fraudulent statement and plaintiffs’ economic damages.) The Court noted that medical researchers consider multiple factors in assessing causation and “[g]iven 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.” The Court also noted that assessing the materiality of adverse event reports is a “fact-specific” inquiry and requires the “consideration of the source, content, and context of the reports.” The Court did note, though, that statistical significance is not irrelevant—only that it is not dispositive of every case.

Instead of asking whether the adverse event reports are “statistically significant,” the Court noted that the relevant inquiry was whether “a *reasonable* investor would have viewed the nondisclosed information ‘as having *significantly* altered the total mix of information.” To satisfy the “total mix” standard (and thus materiality), the Court stated that “the 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 is not limited to statistical significance and can come from ‘the source, content, and

context of the reports.’” Here, the Court noted that the product in question accounted for 70 percent of Matrixx’s sales and “the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx’s leading product.”

CONCLUSION

The Supreme Court’s decision will make it more difficult for defendants in pharmaceutical securities fraud class actions to obtain early dismissal. As a result, such defendants and their insurers may be exposed to significant defense costs that they previously could have avoided if the “statistical significance” requirement had been adopted. In addition, the *Matrixx* decision presents companies with a challenging new dilemma: which adverse event reports need to be disclosed? Disclosing too much has obvious business implications, but disclosing too little will now expose the company to litigation liability.

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