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Supreme Court Rejects Bright Line Test of "Statistical Significance" for Materiality in Securities Claims

BY THE SECURITIES LITIGATION PRACTICE

On March 22, 2011, the Supreme Court of the United States issued a decision in the matter of *Matrixx Initiatives, Inc., et al. v. Siracusano, et al.*, No. 09-1156. The unanimous decision, written by Justice Sotomayor, rejected a bright-line test of statistical significance to determine when information must be disclosed to investors under the securities laws.

The underlying securities fraud complaint alleged that Matrixx, the maker of Zicam Cold Remedy, an over-the-counter product, failed to disclose "adverse event reports" indicating that some users suffered from a loss of smell (anosmia). Matrixx moved to dismiss, arguing that the investors had failed to plead materiality adequately under Section 10(b) of the Securities Exchange Act because they did not allege that the undisclosed reports reflected statistically significant evidence that Zicam caused anosmia. Matrixx argued that because the number of users suffering from anosmia was statistically insignificant, the information was immaterial as a matter of law and the company had no duty to disclose it. The district court granted Matrixx's motion to dismiss, and the Court of Appeals for the Ninth Circuit reversed.

Writing for the Court, Justice Sotomayor held that the materiality of adverse event reports cannot be reduced to a bright-line rule based on statistical significance. The Court reaffirmed the traditional test of *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) and *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976), that the materiality requirement under Section 10(b) of the Exchange Act 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." In *Basic*, the Court had rejected a bright-line test for determining materiality, observing that "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." *Id.*, at 236.

Matrixx argued that adverse event reports regarding a pharmaceutical company's products are not material unless a sufficient number of such reports establishes a statistically significant risk that the product is causing the events. The Court noted this argument rests on the flawed premise that statistical significance is the only reliable indication of causation. A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. "As Matrixx itself concedes, medical experts [often] rely on other evidence to establish an inference of causation." Justice Sotomayor also observed that the Food and Drug Administration ("FDA") does not limit the evidence it considers in reviewing drugs to statistically significant data. "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."

Applying *Basic*'s "total mix" standard in this case, the Court concluded that the investors adequately pleaded materiality. Moreover, the Court held that applying a bright-line test of statistical significance would artificially exclude information that would otherwise be considered significant to a reasonable investor's trading decision. "Although in many cases reasonable investors would not consider reports of adverse events to be material information, respondents have alleged facts plausibly suggesting that reasonable investors would have viewed these particular reports as material."

Notably, the Court cautioned that pharmaceutical manufacturers need not disclose all reports of adverse events. The existence of such adverse events, which can be common occurrences, "says nothing in and of itself about whether the drug is causing the adverse events." Something more than the "mere existence of reports of adverse events" is necessary, the decision states, but that "something more" need not be statistical significance. The issue is whether, in context, a reasonable investor would have viewed reports of adverse events as material even in the absence of statistically significant evidence of a causal link.

The decision also reiterated the principle that, absent a duty to speak, silence cannot be the basis for securities liability; disclosure is required only to make previous statements not misleading: "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." The Court noted that "[t]his is not a case about a handful of anecdotal reports, as Matrixx suggests." Rather, assuming the complaint's allegations to be true, as required at the motion to dismiss stage, the Court found that "Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia." Based on the information allegedly available to Matrixx, the Court found that the complaint alleged facts "suggesting a significant risk to commercial viability of Matrixx's leading product." Since it was substantially likely that a reasonable investor would have viewed this information as having significantly altered the "total mix" of information made available, the investors adequately pleaded a material misrepresentation or omission.

The Court also found that plaintiffs alleged scienter sufficiently. The Court noted that it has not yet determined whether recklessness alone is sufficient to satisfy the scienter requirements, and is saving that question for another day. The Court found that the allegations, "taken collectively," give rise to a "cogent and compelling" inference that Matrixx elected not to disclose the adverse event reports not because it believed they were meaningless but because it understood their likely effect on the market. Therefore, the Court found that respondents had adequately pleaded scienter.

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