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REPORT FROM WASHINGTON

To read the decision in *Matrixx Initiatives, Inc.* v. *Siracusano*, please click here.

The Supreme Court Rejects Bright-Line Rule on Disclosure of Adverse Event Reports

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The Supreme Court issued its decision today in *Matrixx Initiatives, Inc.* v. *Siracusano,* No. 09-1156, rejecting the issuer's proposed bright-line rule that adverse event reports could not be considered material unless they are statistically significant and holding that the plaintiffs stated a valid securities fraud claim. The Court reaffirmed its "total mix" of information standard.

BACKGROUND

The *Matrixx* case relates to alleged misstatements or omissions by Matrixx regarding its main product, Zicam Cold Remedy, a homeopathic remedy used to reduce the severity and duration of the common cold. The plaintiffs allege that Matrixx started receiving multiple reports from physicians and certain academics that some consumers experienced the loss of smell, or anosmia, following the use of Zicam.

On January 30, 2004, the *Dow Jones Newswire* reported that three lawsuits had been filed against Matrixx as a result of complaints that Zicam caused anosmia, allegedly causing a dip in the price of Matrixx's shares. On February 2, 2004, Matrixx issued a press release, contending that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading." On February 6, 2004, a physician stated on a *Good Morning America* segment that Zicam caused anosmia, and Matrixx issued another press release that day, reiterating that Zicam does not cause anosmia. Matrixx's stock price dropped from the previous day's close of $13.04 to $9.94. On February 27, 2004, in a Form 8-K filing with the SEC, Matrixx stated that it had convened a "two-day meeting of physicians and scientists to review current information on smell disorders" in response to the recent claims that Zicam caused anosmia and that the panel found "insufficient scientific evidence at [that] time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

On April 29, 2004, plaintiffs brought suit against Matrixx and certain of its officers in the District of Arizona, alleging that Matrixx's statements about business growth and Zicam's safety were false and misleading. Matrixx moved to dismiss the complaint, arguing that the plaintiffs failed to plead sufficiently the elements of materiality and scienter. The district court dismissed the case due to the plaintiffs' failure to show materiality of the alleged misstatements and/or omissions, holding that "there is no data as to the reliability and accuracy of the user complaints" and "[e]ven if there were . . ., the Court finds 12 user complaints is not statistically significant." No. CV 04 0886 PHX MHM, 2005 WL 3970117, at *7 (Dec. 15, 2005 D. Ariz.). The district court also held that the plaintiffs failed to allege facts showing a strong inference of scienter.

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On appeal, the United States Court of Appeals for the Ninth Circuit reversed and remanded. The Ninth Circuit concluded that "the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality." 585 F. 3d 1167, 1178 (9th Cir. 2009). The Ninth Circuit held that "the district court made a decision that should have been left to the trier of fact." *Id*. at 1179.

Defendant-Petitioner Matrixx filed a petition for a writ of certiorari, which the Supreme Court granted. Before the Supreme Court, Matrixx contended that pharmaceutical companies routinely receive anecdotal reports of alleged adverse effects following the use of drugs, and that these incidents do not establish any reliable facts about the drug's performance or safety in the absence of statistically significant data. Plaintiffs-Respondents countered that materiality should be judged based on the total mix of information available to investors, and that Matrixx sought to change the Court's longstanding analysis of materiality by offering the bright-line standard of statistical significance. The United States, the Securities and Exchange Commission, and the Department of Health and Human Services, represented by the Solicitor General's Office, argued against the bright-line rule proposed by Matrixx and in support of the more flexible standard based on the total mix of information.

"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."

OPINION OF THE COURT

SUMMARY OF THE DECISION

In a unanimous opinion written by Justice Sotomayor, the Supreme Court held that Plaintiffs "have stated a claim under §10(b) and Rule 10b-5" and affirmed the Ninth Circuit.

The Court reiterated that, under *Basic Inc. v. Levinson*, 485 U. S. 224, 231-32 (1988), the "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.'" The Court observed that it had previously rejected a proposed bright-line rule in *Basic* because "[a]ny approach that designates a single fact or occurrence as always determinative of . . . materiality, must necessarily be overinclusive or underinclusive."

Turning to Matrixx's proposed bright-line rule, the Court concluded that it too "would 'artificially exclud[e]' information that 'would otherwise be considered significant to the trading decision of a reasonable investor.'" The Court reasoned that Matrixx's argument rested on the flawed premise that statistical significance is the only reliable indication of causation. The Court noted that both medical experts and the FDA consider factors other than statistically significant data in determining a causal link. These other factors include "strength of the association, "temporal relationship of product use and the event," and "biologic plausibility." "Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant," the Court held, "it stands to reason that in certain cases reasonable investors would as well."

"Application of Basic*'s 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events."*

OPINION OF THE COURT

The Court then made clear that "[a]pplication of *Basic*'s 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events." Noting that the "mere existence of reports of adverse events . . . will not satisfy this standard," the Court reiterated that the key question "remains whether a *reasonable* investor would have viewed the nondisclosed information 'as having *significantly* altered

the "total mix" of information made available.'" The Court also pointed out that "companies can control what they have to disclose" under section 10(b) and Rule 10b-5 by "controlling what they say to the market," emphasizing that these provisions "do not create an affirmative duty to disclose any and all material information," and that disclosure is required "only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'"

"[T]he complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product."

OPINION OF THE COURT

Applying this standard, the Court held that the plaintiffs adequately pleaded materiality. Based on the plaintiffs' allegations, "Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia." Additionally, "[c]onsumers likely would have viewed the risk associated with Zicam (possible loss of smell) as substantially outweighing the benefit of using the product (alleviating cold symptoms), particularly in light of the existence of many alternative products on the market." The Court emphasized that, among other things, "Matrixx told the market that revenues were going to rise by 50 and then 80 percent," and that "reports indicating that Zicam caused anosmia were 'completely unfounded and misleading.'" Noting that Zicam allegedly accounted for 70% of Matrixx's sale, the Court concluded that "the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product."

Turning to scienter, the Court assumed, without deciding, that the "deliberate recklessness" standard applied by the Ninth Circuit was sufficient to establish scienter. The Court held: "The inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that it simply thought the reports did not indicate anything meaningful about adverse reactions." Referencing several specific allegations regarding Matrixx's response to the anecdotal reports, including issuance of a press release suggesting that it had confirmed that Zicam does not cause anosmia even though it had not conducted any studies of Zicam use and anosmia and the scientific evidence at the time was indeterminate, the Court determined that "[t]hese allegations, 'taken collectively,' give rise to a 'cogent and compelling' inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market."

IMPLICATIONS

As in *Basic*, the Supreme Court in *Matrixx* rejected a proposed bright-line rule for determining materiality in securities fraud cases under §10(b) and Rule 10b-5. The Court's decision does not alter the materiality standard set forth in prior case law, and therefore companies should continue to ensure that their disclosures do not contain misstatements or omissions that could be viewed by the reasonable investor as having significantly altered the "total mix" of information made available. Additionally, with respect to the pharmaceutical industry, the Court's decision makes clear that the mere existence of adverse event reports does not automatically satisfy the materiality standard.

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