

SUPREME COURT NOSES THE DOOR OPEN A BIT WIDER FOR PLAINTIFFS IN SECURITIES-FRAUD CLASS ACTIONS

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In *Matrixx Initiatives, Inc. v. Siracusano*,¹ a unanimous Supreme Court declined to adopt a bright-line rule that would have made a drug company's failure to disclose adverse event reports material only if the reports were statistically significant. Instead, the Court reaffirmed the fact-sensitive standard it adopted more than two decades ago: an omission is material under the securities laws only if 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."² The decision is a win for the plaintiffs' bar. Some federal courts, including the U.S. Courts of Appeals for the 1st, 2nd, and 3rd Circuits,³ had adopted the rejected test; now, drug company defendants in those jurisdictions will find it harder to challenge materiality on dispositive motions. The decision also serves as a reminder that companies should consider the possibility of future securities litigation when deciding whether and how to disclose potentially adverse information.

Background

Investors in the drug company Matrixx brought a securities-fraud class action against the company pursuant to Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder. Matrixx manufactured Zicam Cold Remedy, an over-the-counter drug whose active ingredient was zinc gluconate. Zicam was Matrixx's most important product and allegedly accounted for 70 percent of the company's sales. The plaintiffs alleged that for several years Matrixx knew, but did not disclose, that a number of consumers had developed anosmia (the loss of the sense of smell) after using Zicam. According to the complaint, the first report of this potential problem reached Matrixx in 1999. By February 2004, Matrixx had learned that more than 12 Zicam consumers had developed the condition, and that nine of them had filed

product liability actions against the company. Matrixx had also learned that several scientific studies suggested a causal relationship between anosmia and zinc, though not zinc gluconate in particular.

According to the plaintiffs, several statements Matrixx made between October 22, 2003 and February 6, 2004 about Zicam's safety and the company's revenue prospects were materially misleading because Matrixx failed to disclose the reports it had obtained about Zicam users with anosmia. In particular, Matrixx had claimed that Zicam was "poised for growth in the upcoming cough and cold season" and that the company had "very strong momentum."⁴ Matrixx had also offered optimistic revenue guidance, and raised that guidance even higher in January 2004, near the end of the class period. The plaintiffs alleged that Matrixx's projections were materially misleading because Matrixx had failed to disclose that Zicam – which accounted for 70 percent of Matrixx's sales – had been associated with adverse events in more than a dozen users.

Furthermore, the plaintiffs took issue with Matrixx's Form 8-K filing, in which Matrixx offered the generic warning that the institution of any product liability claims against the company could materially harm its financial condition. The plaintiffs alleged that this was misleading because Matrixx knew, but did not disclose, that Zicam users with anosmia had already commenced product liability lawsuits against Matrixx.

In late January 2004, news broke that the FDA was investigating complaints that Matrixx's cold medicine was causing anosmia in some users. After that report, Matrixx's stock fell from \$13.55 to \$11.97 per share. A few days later, Matrixx issued a press release unequivocally professing its belief that the reports about a link between anosmia and Zicam were unfounded; that no clinical trial had ever called into question the safety of zinc gluconate; and that the

ingredient's safety had in fact been well established in two independent clinical trials. Its share price climbed back to \$13.40. The plaintiffs alleged that this press release, which projected an attitude of unquestioned confidence in the safety of Zicam and which suggested that there was no scientific basis for doubting that assessment, was rendered materially misleading by Matrixx's omission of evidence to the contrary.

On Feb. 6, 2004, the information that Matrixx had allegedly been concealing came to light: *Good Morning America* reported on a medical researcher's findings that more than a dozen of his patients had developed anosmia after using Zicam. Matrixx's stock price tumbled to \$9.94 per share.

Subsequently, the plaintiffs filed a securities-fraud class action against Matrixx in federal district court for the District of Arizona. Matrixx filed a motion to dismiss, arguing that the plaintiffs had failed to plead that it had made a material misrepresentation or omission, or had acted with scienter. The district court granted that motion, but the 9th Circuit reversed.

Analysis

In affirming the 9th Circuit's decision, the Supreme Court first rejected Matrixx's argument that "adverse event reports that do not reveal a statistically significant increased risk of adverse events from product use are not material information."⁵ The Court explained that while statistical significance may be *one* "reliable indication" that a particular drug may be the cause of adverse events, it is not the *only* one possible.⁶ Reasonable investors can "act on the basis of evidence of causation that is not statistically significant" but that suggests causation in other ways.⁷ The Court gave examples of other evidence that could suggest causality, such as strength of association, temporal relationship between product use and adverse event, consistency of findings across available data sources, and biological plausibility. The Court concluded that a rule deeming as material only those adverse events that were statistically significant in number would be under-inclusive.

On the other hand, the Court was careful to explain 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" the materiality standard.⁸ Rather, the proper standard ultimately amounts to a "contextual inquiry." To establish materiality, "[s]omething

more" than the mere existence of adverse events is needed. That "something more," however, need not be "statistical significance" but can instead "come from 'the source, content, and context of the reports.'"⁹ "This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link."¹⁰

Applying the test here, the Court held that the adverse events at issue, *when considered in context*, would likely have been material to a reasonable investor. This was "not a case about a handful of anecdotal reports."¹¹ Rather, Matrixx allegedly received reports from three reliable medical professionals about more than 10 patients who had developed a very serious condition after using Zicam – a product that accounted for the vast majority of the company's sales. In at least one case, the effect was immediate. Moreover, numerous scientific studies had demonstrated a causal connection between zinc and anosmia, and Matrixx itself had intended to conduct a study evaluating whether Zicam could cause the condition. The Court concluded that while the adverse event reports may not have been statistically significant in number, the circumstances left no doubt about their importance to investors.

The Court also rejected Matrixx's contention that the plaintiffs had failed to plead scienter with the requisite level of particularity required under the Private Securities Litigation Reform Act. Matrixx had argued that because the plaintiffs had not alleged it was aware of any statistically significant evidence that Zicam caused anosmia, Matrixx had had no basis for believing any of its optimistic statements to be misleading. The Court disagreed. First, it reiterated its point that inferring a causal connection between Zicam and anosmia did not require establishing that the withheld information was statistically significant.

Then it noted that under *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*,¹² a securities-fraud plaintiff adequately alleges scienter if the facts pled give rise to an inference of scienter that is "cogent and at least as compelling as any opposing inference."¹³ Assuming without deciding that the recklessness standard the 9th Circuit applied could supply the requisite scienter, the Court concluded that the plaintiffs had adequately pled scienter. According to the complaint, during the class period Matrixx hired a consultant to investigate the alleged causal relationship. This suggested to the Court that

Matrixx had serious concerns about the drug's safety. The Court concluded further that the "[m]ost significant" factor supporting an inference of scienter was Matrixx's issuance of a press release implying that there was no scientific basis for doubting that zinc gluconate was safe, when in fact Matrixx was aware of the existence of studies suggesting the contrary.¹⁴ Taken together, these and other circumstances alleged by the plaintiffs sufficed to plead scienter under *Tellabs*.

Implications

Adverse event reports are a daily occurrence in the pharmaceutical industry. As the Court noted, in 2009 alone about 500,000 adverse event reports reached the FDA. Unfortunately, the *Matrixx* opinion provides no definitive guidance to drug companies struggling to decide just which of these events they must disclose to investors. Instead, companies must carefully examine "the source, content, and context of the reports," and assess whether the reports plus the circumstances surrounding them cross the materiality threshold. In conducting such a fact-sensitive analysis, the advice of counsel with practical experience in litigating securities-fraud cases may prove crucial.

More broadly, *Matrixx* illustrates the importance of a principle that too often goes ignored: the securities laws "do not create an affirmative duty to disclose any and all material information."¹⁵ Absent a special duty of disclosure (such as a fiduciary may have), the obligation to disclose attaches only when a company affirmatively makes a statement that would be misleading unless other information is disclosed. *Matrixx* exacerbated its legal problems by trumpeting scientific studies supporting the safety of Zicam without disclosing the existence of other studies suggesting the contrary. If *Matrixx* was not prepared to address the unfavorable studies, it could have put off speaking about the favorable studies. Although it is understandable in today's world of instant information that a company's initial reaction to adverse news is often to issue a statement as quickly as possible, companies would do well to consider carefully whether they are prepared to speak and what they should say.

While there are often good business reasons for responding quickly and directly to unfavorable news, companies should craft their statement with care and assess its capacity to mislead in its entire context, paying special attention to what other information they may need to disclose. A carefully crafted statement that complies with the securities laws may not prevent plaintiffs from bringing suit, but it will enhance the company's ability to avoid liability and defeat the suit at an early stage of the litigation. Now that the Supreme Court has confirmed that the totality-of-the-circumstances materiality standard is here to stay, such a considered approach is more important than ever.

¹ 563 U.S. ____ (2011).

² *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

³ See *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1st Cir. 2008); *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36, 41 (2d Cir. 2000); *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000). Then-Judge Alito wrote the opinion of the court in *Stafford*.

⁴ *Matrixx*, 563 U.S. at ____ (slip op. at 4).

⁵ *Id.* at ____ (slip op. at 9).

⁶ *Id.* at ____ (slip op. at 11).

⁷ *Id.* at ____ (slip op. at 15).

⁸ *Id.* at ____ (slip op. at 16).

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.* at ____ (slip op. at 16-17).

¹² 551 U.S. 308 (2007).

¹³ *Id.* at 314.

¹⁴ *Matrixx*, 563 U.S. at ____ (slip op. at 21).

¹⁵ *Id.* at ____ (slip op. at 16).