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U.S. SUPREME COURT RULES THAT A DRUG'S ADVERSE EVENT REPORTS MAY BE MATERIAL TO INVESTORS EVEN THOUGH NOT "STATISTICALLY SIGNIFICANT"

On March 22, 2011, the U.S. Supreme Court issued its long-awaited opinion in *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156). At issue in the case was whether a securities-fraud class action could be based on a pharmaceutical company's failure to disclose adverse event reports ("AERs") related to one of its products, even if the number of adverse events was not statistically significant.

Under the federal securities laws, companies can be liable for misrepresentations or omissions to disclose information only if the information itself is "material"—that is, information that a reasonable investor would want to know before making an investment decision. In *Matrixx*, the company argued for a "bright line" test, under which information in AERs could be considered material only if the frequency of adverse events had crossed the threshold of statistical significance.

In an opinion by Justice Sonia Sotomayor, the justices unanimously disagreed. Echoing the Court's 1988 decision in *Basic Inc. v. Levinson*, they held that the question of materiality required a more nuanced determination of the underlying facts and circumstances. Thus, the allegations of this complaint, if true, were sufficient to establish that undisclosed information about AERs was material to investors.

BACKGROUND OF THE CASE

Matrixx Initiatives ("Matrixx") develops, manufactures, and markets over-the-counter pharmaceuticals, including Zicam Cold Remedy ("Zicam"), which accounted for about 70 percent of its sales. The active ingredient of Zicam was zinc gluconate. Beginning in 1999, the company became aware of clinical reports, studies, and patient complaints suggesting that a number of individuals had suffered anosmia, loss of the sense of smell, after using Zicam. The company's vice president for R&D became aware of abstracts from earlier studies suggesting the toxicity

of zinc, and in about September 2003, the company learned in advance of a presentation by Dr. Bruce Jafek at the American Rhinologic Society in which he reported that 11 patients had suffered anosmia after using Zicam. The company successfully prevented Dr. Jafek from referring to the trade name of its product in a poster presented at the meeting.

After learning of Dr. Jafek's findings and presentation, the company issued optimistic public statements, announcing that it was "poised for growth in the upcoming cough and cold season" and "had very strong momentum." It initially projected that revenues would be "up in excess of 50%" and later revised that estimate to predict an 80 percent increase. In a Form 10-Q filed in November 2003, the company warned of the potential adverse effects of product liability claims, "whether or not proven to be valid," but did not disclose the information it had already received about possible links between Zicam and anosmia, or the fact that two plaintiffs had already filed product liability lawsuits against Matrixx relating to Zicam and anosmia.

In late January 2004 it was reported in the media that, in light of several product liability lawsuits, the FDA was investigating whether the product was causing patients to lose their sense of smell. Matrixx's share price fell by 12 percent the next day. In response, Matrixx issued a press release asserting its belief that statements that Zicam caused anosmia were "completely unfounded and misleading" and that the safety and efficacy of zinc gluconate had been well established by two double-blind, placebo-controlled randomized clinical trials. Following this release, the stock price recovered virtually all of its earlier loss.

In early February, a nationally broadcast morning news program reported on Dr. Jafek's findings and also reported that four product liability suits had been filed against the company. The stock price fell 25 percent following this report, and the company issued a press release similar to the previous one. Later that month, the company filed a Form 8-K stating that it had convened a panel of experts "to review current information on smell disorders" and that "in the opinion of the panel, there is insufficient evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

The plaintiffs filed an action in the U.S. District Court for the District of Arizona claiming that the defendants had violated Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 by making untrue statements of fact and by making statements that were misleading because they failed to disclose material facts. The district court granted the defendants' motion to dismiss the complaint; the Ninth Circuit Court of Appeals reversed, finding that the plaintiffs' allegations were sufficient to state a claim. In its March 22, 2011, decision, the Supreme Court affirmed, agreeing that the complaint was sufficient to allow the plaintiffs to proceed to discovery and a possible trial.

THE SUPREME COURT'S DECISION: MATERIALITY

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege: (1) the misrepresentation or omission of a material fact; (2) that the defendant acted with *scienter*, an intent to deceive, manipulate, or defraud; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) the plaintiff's reliance on the statement; (5) economic loss; and (6) loss causation.[1] The key questions facing the Court in *Matrixx* involved the first two elements: whether the nondisclosure of the AERs was material to investors and whether the company and its officers had acted with *scienter*.

Under long-settled precedent, a fact is considered material 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 Supreme Court has consistently resisted efforts to establish "bright line" tests that

1 *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

2 *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988), quoting *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

would make it clear when information is material and must therefore be disclosed. In *Basic*, for example, the Court refused to rule that information about a company's merger negotiations became material only after the parties had reached an agreement in principle, deciding instead that the fact that a company was in merger negotiations might well be material, depending on a range of factors, including the stage of the negotiations, the significance of the event to the company, and the perceived likelihood that a deal might be reached. The Court explicitly rejected "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality."[3]

In *Matrixx*, the company argued that information concerning Zicam's AERs could not be material to investors unless the information showed a statistically significant correlation between use of the product and anosmia. Once again, the Court rejected a bright-line test, finding that under the circumstances alleged in the complaint, the AERs "significantly altered the 'total mix' " of information. As before, the Court cautioned that this was a fact-specific determination. It noted, however, that in this case there were ample facts to suggest that the AER information was significant. Among other things, medical experts, the FDA, and courts often rely on evidence that falls short of statistical significance to establish an inference of causation. The materiality of the AERs in this case could be established by considering the source, content, and context of the information available to the company, which included studies conducted over several decades and a scientific presentation by a credible clinician.

The Court was careful to point out that its decision does not mean pharmaceutical manufacturers must disclose all AERs. The existence of an adverse event, standing alone, does not mean that the drug caused that event. "Something more is needed, but that something more is not limited to statistical significance . . . ."[4] Here, the "something more" was supplied by a combination of historical research studies, contemporary studies, and professional presentations that established evidence of a link between Zicam and anosmia, as well as the fact that Matrixx had not conducted any studies of its own specifically to prove or disprove that link.

In addition, the Court reiterated that mere silence does not violate the securities laws unless one has a duty to speak. On the other hand, the Court also reiterated that when a company chooses to speakÐas the company did here when discussing its "momentum" and forecasting increasing revenuesÐa failure to disclose material information may give rise to liability.

SCIENTER

In contrast to its extended treatment of the question of materiality, the Court's discussion of *scienter* was brief. To establish *scienter* under Section 10(b), a plaintiff must allege specific facts that give rise to an inference of *scienter* that is "cogent and at least as compelling as any opposing inference."[5] Matrixx once again relied on the notion of statistical significance as a response to the plaintiffs' scienter allegations, arguing that the most logical inference from the facts alleged was that it did not disclose the AERs because it thought they did not convey meaningful information.

The Court found that the fact that a causal link had not been statistically proved did not sufficiently explain the company's efforts to deny that a link might exist. It held that a contrary inference was at least as compelling: that the company resisted disclosing information about AERs because it perceived that the market would be concerned about adverse reports concerning its primary source of revenue. In support of this conclusion, the Court referred to allegations that Matrixx was sufficiently concerned about the AERs that it hired a consultant to review the product in 2002, asked clinicians to participate in animal studies at about the same time, and successfully prevented Dr. Jafek from

3 *Basic Inc.*, 485 U.S. at 236.

4 *Matrixx Initiatives, Inc. v. Siracusano*, ___ U.S. ___ (2011), slip op. at 16.

5 *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

using the name "Zicam" in his presentation. Most important, in the Court's view, was the allegation that the company had issued press releases suggesting that studies confirmed that Zicam does not cause anosmia, when in fact it had not conducted any studies related to anosmia and, as it later acknowledged, the scientific evidence was insufficient to determine whether a causal link existed.

Like its discussion of materiality, the Court's holding on *scienter* did not break new ground. Nor was it surprising: given the company's alleged awareness for several years of information suggesting a causal link between Zicam and anosmia and its efforts to prevent the association of its product with the problem, the Court had little trouble deciding that these allegations, if proved, could support a claim that Matrixx was trying to conceal a problem that investors had a right to know about.

WHAT DOES THE DECISION MEAN FOR COMPANIES?

In the aftermath of *Matrixx*, one can expect that plaintiffs' attorneys will argue that public companies always, or nearly always, have a duty to report adverse incidents to the public. The argument will likely be advanced that companies must immediately "come clean" with information about a broad array of untoward events.

Such claims, however, are no more likely to be upheld by the courts after *Matrixx* than they were before. The Supreme Court, after all, left undisturbed the pillars of its securities-fraud jurisprudence. Most notably, it reiterated that companies do not have a generalized duty to speak, though they must speak truthfully when they do, and that questions of materiality are simply not susceptible to "bright line" tests. This latter doctrine can, at times, be frustrating to those who yearn for simple rules to guide decisions about what to disclose and when. Companies constantly learn of complaints about the quality and safety of their products and face difficult disclosure decisions that are sometimes based on information that is developing in real time.

The Court made it clear that "[t]his is not a case about a handful of anecdotal reports."[6] Accordingly, companies should not have to disclose every adverse incident or complaint about their products. At the same time, they cannot "manage" a developing problem with an important product by denying that it exists or by ignoring it while issuing rosy forecasts. A key problem for Matrixx, in the Court's view, was its strong external denials of the existence of an issue, which appeared to be at odds with its internal state of knowledge and concern. Accordingly, disclosure decisions should continue to be made as they were before *Matrixx*—on the basis of common sense and a thorough understanding of the meaning and importance of the information in question.

The case stands most clearly for the proposition that when making disclosure decisions, it is risky to assume that a fact or causal link is immaterial to investors unless it can be scientifically proved or disproved. Just as people make decisions every day based on less than perfect information, investors consider information even though its meaning may yet be unclear or uncertain.

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6 *Matrixx Initiatives*, slip op. at 16–17.

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