Alerts and Updates

U.S. SUPREME COURT IN MATRIXX: NO BRIGHT LINE FOR "MATERIALITY" IN A SECURITIES FRAUD CLAIM

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On March 22, 2011, the U.S. Supreme Court unanimously concluded in the securities fraud class action *Matrixx Initiatives, Inc. v. Siracusano*[1] that the materiality of adverse-event reports cannot be reduced to a bright-line rule. The Court reaffirmed its decision in *Basic Inc. v. Levinson*[2] that the materiality requirement in a private action under Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act) and Rule 10b-5 adopted thereunder 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 further determined that evidence of statistical significance is not required to establish either the materiality of a misstatement or omission, or the element of scienter to properly plead a securities fraud claim under Section 10(b) and Rule 10b-5.

The complaint alleged that Matrixx Initiatives, Inc. (Matrixx), maker of Zicam Cold Remedy (Zicam), violated Section 10(b) and Rule 10b-5 by failing to disclose a possible link between the usage of Zicam and the loss of a sense of smell—or anosmia—thereby rendering public statements Matrixx subsequently made regarding Zicam misleading.[3] The complaint maintained that Zicam accounted for approximately 70 percent of Matrixx's sales, and that Matrixx had received reports from both medical experts and researchers reporting a possible link between Zicam and anosmia.[4] Furthermore, the complaint contended that subsequent to receiving these medical reports suggesting a causal link between Zicam and anosmia—as well as the filing of two products liability lawsuits against Matrixx alleging Zicam damaged the plaintiffs' sense of smell—Matrixx published statements projecting strong growth and a greater-than 50-percent increase in revenues, and later amended that projection to a greater-than 80-percent increase in revenues.

In its Form 10-Q filed in November 2003, Matrixx referred to the potential adverse effect of any products liability claims brought against the company, but did not mention that two suits regarding Zicam had already been filed. Additionally, after a Dow Jones Newswires report that the U.S. Food and Drug Administration (FDA) was looking into complaints that Zicam might be linked to anosmia and the subsequent fall of Matrixx's stock from $13.55 per share to $11.97 per share, Matrixx issued a press release,[5] rejecting the notion that Zicam was linked to anosmia and stating that the safety and efficacy of zinc gluconate—the main component of Zicam—was well-established. The day after Matrixx issued this press release, Matrixx's stock rebounded to $13.40 per share.

The Court dismissed Matrixx's efforts to urge a bright-line rule for purposes of determining materiality. In doing so, the Court concluded that a reasonable investor, in light of the specific facts and circumstances, could consider the information made available as *significantly altered* by the nondisclosed information, and that the complaint alleged facts that pose considerable risk to Matrixx's leading revenue generator. Noting that the mere existence of reports of adverse events does not satisfy the *Basic* standard and that something more is necessary—but that statistical significance is not required—the Court further explained that medical experts and the FDA often rely on data that are not statistically significant for inferring causation; and therefore, reasonable investors may do so as well.[6]

The Court also found that statistically significant data are unnecessary to prove the element of scienter, or the intent to deceive, manipulate or defraud,[7] but concluded that, taken as a whole, the allegations of the complaint could lead to a reasonable inference that Matrixx chose not to disclose the reports of adverse events or the products liability lawsuits because it was aware of their potentially negative impact on its leading product.[8]

Conclusion

The *Matrixx* decision raises questions about when disclosure of reports of adverse events is required and how organizations can take prophylactic measures to prevent similar securities fraud claims.[9] As the Supreme Court concluded, the threshold is below statistically significant data; organizations should consider how the information would impact a reasonable investor's view of the "total mix" of information already made public.[10]

A key takeaway from this decision is that a public company needs to monitor employees and agents who speak on its behalf and to vet public statements before their release to ensure that the statements do not improperly alter the total mix of information and unduly expose the company to securities fraud liability.

For Further Information

If you have any questions about the foregoing decision or how this decision may impact your organization, please contact one of the members of the Corporate Practice Group, one of the members of the Trial Practice Group or the lawyer in the firm with whom you are regularly in contact.

Notes

1. *Matrixx Initiatives, Inc. v. Siracusano*, 2011 U.S. LEXIS 2416 (U.S. Mar. 22, 2011).

2. 485 U.S. 224, 231–232 (1988).

3. In 1999, Dr. Alan Hirsch, neurological director of the Smell & Taste Treatment and Research Foundation, Ltd., called Matrixx's customer-service line after discovering a possible link between Zicam nasal gel and a loss of smell in a cluster of his patients. He also told a Matrixx employee that "previous studies had demonstrated that intranasal application of zinc could be problematic."

4. The Court noted that: "In September 2002, Timothy Clarot, Matrixx's vice president for research and development, called Miriam Linschoten, Ph.D., at the University of Colorado Health Sciences Center after receiving a complaint from a person Linschoten was treating who had lost her sense of smell after using Zicam. Clarot informed Linschoten that Matrixx had received similar complaints from customers. Linschoten drew Clarot's attention to 'previous studies linking zinc sulfate to loss of smell.'. . . Clarot gave her the impression that he had not heard of the studies. She asked Clarot whether Matrixx had done any studies of its own; he responded that it had not but that it had hired a consultant to review the product. Soon thereafter, Linschoten sent Clarot abstracts of the studies she had mentioned. Research from the 1930's and 1980's had confirmed 'zinc's toxicity.'"

5. Press release dated February 2, 2004, stated: "All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.

> "In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.
> "A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants."

Additionally, on February 19, 2004, Matrixx filed a Form 8-K with the SEC stating that it had "'convened a two-day meeting of physicians and scientists to review current information on smell disorders.'" According to the Form 8-K, "'In the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.'"

6. The Court stated: "Like the defendant in *Basic*, Matrixx urges us to adopt 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 a statistically significant risk that the product is in fact causing the events. Absent statistical significance, Matrixx argues, adverse event reports provide only 'anecdotal' evidence that 'the user of a drug experienced an adverse event at some point during or following the use of that drug.'. . . Accordingly, it contends, reasonable investors would not consider such reports relevant unless they are statistically significant because only then do they 'reflect a scientifically reliable basis for inferring a potential causal link between product use and the adverse event.'"

7. The Court noted that it was not deciding whether a showing of deliberate recklessness satisfies the scienter requirement as the issue was not raised by *Matrixx*.

8. The Court stated: "The question remains whether a *reasonable* investor would have viewed the nondisclosed information 'as having *significantly* altered the "total mix" of information made available.'" *Basic*, 485 U.S., at 232 (quoting *TSC Industries*, 426 U.S., at 449; emphasis added). For the reasons just stated, 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 more is not limited to statistical significance and can come from 'the source, content, and context of the reports.'. . .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."

9. The Court noted that as of the class period, Matrixx had not conducted any studies of its own on the potential link between anosmia and the use of Zicam, and that Matrixx's vice president of research and development was made aware of previous studies that suggested a causal link. Therefore, the Court concluded that the complaint alleged sufficient facts to reasonably infer that Matrixx had no basis to reject the assertion that there could possibly be a link between its leading product and anosmia.

10. "We believe that these allegations suffice to 'raise a reasonable expectation that discovery will reveal evidence' satisfying the materiality requirement, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007), and to 'allo[w] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,' *Iqbal*, 556 U.S., at __ (slip op., at 14). The information provided to Matrixx by medical experts revealed a plausible causal relationship between Zicam Cold Remedy and anosmia. Consumers 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. Importantly, Zicam Cold Remedy allegedly accounted for 70 percent of Matrixx's sales. Viewing the allegations of the complaint as a whole, the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product."
The Court further opined that "Assuming the complaint's allegations to be true, however, Matrixx had information indicating a significant risk to its leading revenue-generating product. Matrixx also stated that reports indicating that Zicam caused anosmia were 'completely unfounded and misleading' and that 'the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have well been established.'. . . Importantly, however, Matrixx had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link. In fact, as Matrixx later revealed, the scientific evidence at that time was 'insufficient. . . to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.'"