The Legal Intelligencer

THE OLDEST LAW JOURNAL IN THE UNITED STATES 1843-2011

PHILADELPHIA, THURSDAY, APRIL 28, 2011 VOL 243 • NO. 82 An ALM Publication

SECURITIES LAW

'Matrixx,' Materiality and Statistical Significance

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Special to the Legal

In *Matrixx Initiatives Inc. v. Siracusano*, the U.S. Supreme Court reviewed its "total mix" standard for materiality in Rule 10b-5 cases. Under this standard, information is material to an investor 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." (See the Supreme Court's 1988 opinion in *Basic Inc. v. Levinson*.)

Pharmaceutical company defendant Matrixx argued that reports of adverse events concerning its drug, Zicam, a homeopathic cold remedy, were not material because there was no statistically significant evidence linking the adverse events to Zicam. Writing for a unanimous court, Justice Sonia Sotomayor rejected this "statistically significant" standard, strongly reaffirming *Basic*.

The initial round of decisions applying *Matrixx* in the pharmaceutical and financial industries demonstrate its reach and relevance to the legal and business communities.

THE 'MATRIXX' CASE

In *Matrixx*, a putative class of Matrixx investors argued that the company had artificially elevated Matrixx's share price through material misrepresentations about Zicam, the chief source of the company's profits. Specifically, the plaintiffs asserted that Matrixx misled investors about the company's prospects and Zicam's safety, despite receiving between 1999 and 2003 "adverse event reports" that the drug may have caused a loss of smell (anosmia). By early 2004, the national media, including "Good Morning America," began reporting on links between Zicam and anosmia, and the company's stock price tumbled.

The federal district court dismissed the complaint on the ground that the adverse event reports could not be material as a matter of law because they were not alleged to be statistically significant evidence of a causal link between Zicam and anosmia. This standard already had been adopted by several federal courts, including the 2nd U.S. Circuit Court of Appeals and the 3rd Circuit, in a decision by then-Judge Samuel Alito. On appeal, the 9th Circuit reversed, rejecting the "statistically significant" standard. The Supreme Court granted certiorari to resolve the circuit split and heard argument on Jan. 10.

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KEY HOLDINGS

The question presented to the Supreme Court was "whether a plaintiff can state a claim for securities fraud ... based on a pharmaceutical company's failure to disclose reports of adverse events associated with a product if the reports do not disclose a statistically significant number of adverse events." Seeking to overturn an "anti-business" decision by the 9th Circuit on grounds that Alito had expressly embraced as a circuit court judge, Matrixx and its nine supporting amici may have thought Matrixx had a reasonably good chance of success at the Supreme Court. Their hope was misplaced.

Contrary to the conventional wisdom that the Supreme Court is steadfastly pro-business and engaged in a campaign to increase plaintiffs' pleading burdens (e.g., *Twombly* and *Iqbal*), the court held that "a statistically significant number of adverse events" was not necessary for a plaintiff to state a claim for securities fraud, strongly reaffirming the "total mix of information" test articulated in *Basic*. In reaffirming this standard, the court emphasized that, for the purposes of assessing materiality, any bright-line rules would be inappropriate because such rules "would 'artificially exclud[e]'" information that "'would otherwise be considered significant to the trading decision of a reasonable investor.'" Therefore, the court rejected the "statistically significant" standard for the materiality of advance event reports.

Applying the "total mix" test, the court held that the *Matrixx* plaintiffs had met their burden of adequately pleading materiality. After listing the different reports of adverse events that the company had received from patients, researchers and products liability plaintiffs, the court held that the plaintiffs made a sufficient showing that "Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia," and that this was information that a reasonable investor would want to know.

REJECTING BRIGHT LINES IN FAVOR OF CONTEXT

The argument can be made that bright-line rules are important, particularly in shaping business law, because they provide clarity and predictability. Bright-line rules increase parties' certainty about their legal position, allowing them to act or negotiate accordingly.

The unanimous Supreme Court rejected this approach to Rule 10b-5 materiality, emphasizing that materiality is contextual and unfit for bright-line rules. Though the bright-line "statistically significant" rule would provide clarity, the court held that such clarity was outweighed by the danger that the rule would be "overinclusive or underinclusive."

The court emphasized that Matrixx's proposed standard would improperly exclude information about adverse event reports that,

while not statistically significant, are relied upon by the FDA and medical researchers in making regulatory and medical drug safety decisions. Coming unanimously from a relatively pro-business Supreme Court, litigants and judges should take special note of the *Matrixx* court's enthusiastic embrace of the "total mix."

LIMITED GUIDANCE

According to the FDA, pharmaceutical companies receive hundreds of thousands of adverse event reports each year. Although "something more" than the "mere existence" of an adverse event triggers a reporting obligation, the court was disappointingly opaque in its analysis, explaining "that something more ... can come from 'the source, content, and context of the reports.'" A close read of the opinion, however, offers some guidance.

• **Research matters.** The court stressed that during the relevant period, Matrixx lacked internal research rebutting the link between Zicam and anosmia. Thus, the company's renunciation of the causal link suggested by the adverse event reports lacked force. This emphasis suggests that internal research contradicting or refuting adverse event reports might render such information immaterial. Companies should take this into account when analyzing the materiality of adverse event reports.

• **The (legal) benefit of silence.** The court emphasized that § 10(b) of the Exchange Act and Rule 10b-5 do not create affirmative disclosure duties, noting that "companies can control what they have to disclose under these provisions by controlling what they say to the market." Thus, the court implied that Matrixx could have avoided securities fraud liability by ignoring, or at least not forcefully rebutting, the public reports of adverse event reports. This may be of little practical benefit as it is myopic to ignore the business risks of remaining silent to a drum beat of negative news reports, such as the "Good Morning America" story criticizing Zicam.

This lesson was reinforced by a recent case out of the U.S. District Court for the Southern District of New York, in which the court applied *Matrixx* in holding that although a pharmaceutical company may have had no affirmative obligation to make any disclosures, because it was otherwise "regularly commenting about a pending drug application" it had "an unwaiveable duty to be both accurate and complete when it spoke to investors." (See the March 30 opinion *In re Sanofi-Aventis Securities Litigation*.)

• **Consider the source of the adverse event reports.** As was made clear at oral argument and in the Supreme Court's opinion, not all adverse event reports are created equal, and credibility can derive from the source of the report. The court noted that the Zicam-related adverse event reports were not just patient complaints or lawsuits (although Matrixx faced both), but also arose from scientific research. The court emphasized that the company was aware of a medical researcher's presentation suggesting a link between Zicam and anosmia, as well as previous studies showing a "biological causal link between intranasal application of zinc and anosmia." Appropriately, the type and source of an adverse event report matters in assessing the report's materiality, reinforcing that a company's response should be guided in part by the credibility of the report.

POTENTIAL IMPACT BEYOND THE PHARMACEUTICAL INDUSTRY

Though *Matrixx* is specific to adverse event reports in the pharmaceutical industry, the court's materiality analysis raises issues faced by all public companies. For example, a March 31 opinion from the U.S. District Court for the Southern District of New York, *In re Wachovia Equity Securities Litigation*, applied *Matrixx* in the context of the financial industry. The opinion cited *Matrixx* for the proposition that "the materiality inquiry 'is not limited to statistical significance.'"

Applying the 'total mix' test, the U.S. Supreme Court held that the Matrixx *plaintiffs had met their burden of adequately pleading materiality.*

In particular, the underlying conundrum faced by *Matrixx* — whether the company's knowledge about potential problems or difficulties rose to the level of materiality — is commonplace across all industries. Thus, three broader lessons can be drawn from *Matrixx* that extend well beyond the world of pharmaceuticals.

• **Other contexts.** Pharmaceutical adverse event reports are a species of a broader genus: Similar materiality determinations must be made whenever any company learns of isolated problems, such as a car company getting isolated reports of manufacturing defects or a financial institution receiving word of seemingly isolated instances of fraudulent activity. *Matrixx* may well have broad application and it would be a mistake to cabin the case to a pharmaceutical niche.

• **The 'Reasonable Shareholder.'** Interestingly, the court placed the "reasonable shareholder" on similar footing with medical professionals and regulators in assessing materiality. Watch out. In so doing, the court may have laid the foundation in future cases for raising the bar for what is expected of the "reasonable shareholder."

Because investors vary, courts consider the impact of information on the "reasonable shareholder" who acts as proxy for all shareholders to analyze whether securities laws are violated. The characteristics of the "reasonable shareholder" thus make a big difference to securities law.

In *Matrixx*, the court reasoned that if the FDA or medical researchers would rely on certain information, so would the "reasonable investor." In so doing, the court appears to have elevated the "reasonable shareholder" to a level of sophistication comparable to knowledgeable scientists and regulators, at least with respect to assessing causality and materiality. It remains to be seen whether, and if so how, federal courts will apply this "reasonable shareholder" ability in future cases. If courts decide that the "reasonable shareholder" has a graduate degree, *Matrixx* could have unintended consequences going forward.

• **Future role of statistical significance.** The court held that statistical significance is not necessary to establish materiality at the pleading stage. The court did not opine on whether non-statistically significant events could demonstrate materiality at trial. Further, and more importantly, the court did not opine on the role of statistical significance in other contexts.

Courts now routinely consider the statistical significance of various events in assessing liability and damages. In a multiple regression explaining job promotion or wages, for example, experts opine about whether a variable capturing gender or race is statistically significant. If statistically significant, liability is indicated; if not, liability is not. Similarly, in assessing damages, a party may introduce a complex statistical analysis and rely on the statistical significance — or not — of a key variable. Those analyses make good sense and remain unaffected. The court's ruling in *Matrixx* says nothing about this widespread use of statistical evidence. •