Matrixx Initiatives, Inc. v. Siracusano: U.S. Supreme Court Rejects "Statistical Significance" as Threshold for Required Disclosure of Drug Adverse Event Reports

Is a manufacturer of a pharmaceutical product effectively shielded from securities fraud claims if it fails to disclose adverse events associated with a key product unless the number of events is statistically significant? Presented with this proposition in *Matrixx Initiatives, Inc. v. Siracusano*, the U.S. Supreme Court unanimously declined to recognize such a bright-line rule.

In *Matrixx*, the Court was asked to rule on the Ninth Circuit's reversal of the District Court's grant of a motion to dismiss a securities fraud class action lawsuit filed against Matrixx Initiatives, Inc. ("Matrixx") and certain of its executives on behalf of purchasers of Matrixx's securities during a period of approximately 3½ months commencing in late October 2003. In rejecting the motion to dismiss and the bright-line rule advocated by Matrixx, the Court relied on its prior decisions analyzing the materiality and scienter (intent) elements of a securities fraud claim under §10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated by the Securities and Exchange Commission thereunder. While such an analysis would not ordinarily seem noteworthy, a close reading of the decision in *Matrixx* suggests that pharmaceutical issuers (1) may be at risk for liability if they delay or decline to acknowledge adverse events and/or research with respect to their key products, regardless of whether they believe such events and/or research to be relevant and valid and (2) may be viewed as acting with the market for their securities in mind when they attempt to protect the market position of a key product.

Background[1]

Plaintiffs' complaint is based on public statements made by Matrixx, a maker of over-the-counter pharmaceutical products, with respect to its Zicam Cold Remedy product ("Zicam") that utilized zinc gluconate as its active ingredient and accounted for approximately 70% of Matrixx's sales. Plaintiffs claim that Matrixx's statements regarding Zicam during the class period were misleading in that they did not disclose reports Matrixx received about consumers who lost their sense of smell ("anosmia") after using the product.

The first reports of anosmia reached Matrixx in 1999 through a call made by a research doctor to Matrixx's customer service line reporting the incidence of anosmia in "a cluster of his patients" who had used Zicam, and directing Matrixx to prior research that showed a causal link between intranasal application of zinc and anosmia. A few years later, an executive officer in Matrixx's research and development group had a discussion with another doctor regarding complaints that Zicam led to anosmia, during which the officer indicated that Matrixx had not done any studies but had hired a consultant to look into it. Later Matrixx became aware that the same doctor and a colleague would be presenting findings at the American Rhinologic Society linking ten cases of anosmia to Zicam (the "ARS Presentation Findings") and successfully prevented those doctors from referring to Zicam by name in their presentation. During the next few months, nine plaintiffs filed four product liability lawsuits alleging that Zicam had damaged their sense of smell. During this same period, Matrixx made positive statements regarding its projected results for Zicam and the company itself in its SEC filings, and although it included generic disclosure that it was subject to product liability risks,

[1] Because of the procedural posture of the case, the Court was required to assume that all facts alleged by the plaintiffs in its complaint were true.

it did not specifically identify the lawsuits or make any disclosure regarding the information it had received with respect to the possible anosmia link.

Additionally, in response to a Dow Jones news report on January 30, 2004 that the United States Food and Drug Administration ("FDA") was looking into complaints regarding Zicam-induced anosmia, and later in response to a "Good Morning America" program aired several days later that highlighted the ARS Presentation Findings, Matrixx issued press releases stating its belief in the safety of Zicam, its belief that contrary reports were misleading and noting the absence of any such findings in its clinical trials for the drug. Matrixx's share price fluctuated down in response to the reports, and up in response to the first, but not the second, press release.

Approximately two weeks after the "Good Morning America" program, Matrixx filed a Current Report on Form 8-K with the SEC indicating that it had convened a two-day meeting of physicians and scientists to review the possible anosmia link, and that in the opinion of the panel, insufficient evidence existed to confirm or refute the link.

Plaintiffs subsequently filed a securities fraud class action lawsuit claiming that Matrixx had violated §10(b) and Rule 10b-5 by inadequately disclosing the anosmia reports to investors in an effort to maintain artificially high prices for Matrixx's securities.

Rejection of Bright-Line Test

In its motion to dismiss the complaint, Matrixx asserted that plaintiffs failed to plead both the "material misrepresentation" and "scienter" elements of a securities fraud claim, because they had not alleged that the reports Matrixx received of an anosmia link to Zicam "reveal[ed] a statistically significant increased risk of adverse effects from product use." The Court flatly rejected this argument.

With respect to materiality, the Court applied the materiality standard set forth in *Basic v. Levinson*: a fact is material if a reasonable investor would have viewed the fact as having significantly altered the "total mix" of information made available. Although Matrixx argued that a reasonable investor would pay attention only to a statistically significant number of events, the Court noted that there were other accepted ways to establish that a drug caused, or was likely to cause, an adverse effect. The Court noted that in assessing the safety risk of a product, the FDA considers many other factors beyond statistically significant adverse effect data, including, for example, biological plausibility. The Court also noted that the FDA can require side effect labeling "as soon as there is reasonable evidence of an association of a serious hazard with a drug," without proof of causation. Moreover, the Court reiterated its view in *Basic* that adopting a bright-line rule in the context of a materiality determination would "artificially exclud[e] from the definition of materiality information ... which would otherwise be considered significant to the trading decision of a reasonable investor." Given that in the pharmaceutical industry adverse event reports are a daily occurrence, the Court stressed that the "total mix" standard does not require companies to disclose every adverse event report they receive. The Court said there must be "something more" to require a company to disclose, which can be determined by looking at "the source, content, and context of the reports." The significance of the product to the issuer (Zicam accounted for 70% of Matrixx's revenues) is also an important factor.

With respect to scienter, the Court noted that under the Private Securities Litigation Reform Act, a complaint adequately pleads scienter if a reasonable person, upon examination of the facts, could find the inference of scienter cogent and as compelling as any opposing inference one could draw. According to the Court, the inference that Matrixx acted with the requisite intent was at least as compelling, if not more compelling, than the inference proffered by Matrixx that they did not disclose the reports "simply because [Matrixx] believed they were far too few ... to indicate anything meaningful about adverse reactions to use of Zicam," or an inference that Matrixx was waiting to investigate the issue more fully before making any statement. Most

troubling to the Court was the issuance of a press release suggesting that the absence of a link to anosmia had been conclusively established, although Matrixx had not conducted any studies to that effect.

In its decision, the Court emphasized that companies need not disclose all material information they possess, since Rule 10b-5 does not create an affirmative duty to disclose, and without a duty to disclose, companies may remain silent. Companies must only disclose material information that makes their other statements to the market, in the light of the circumstances under which they were made, not misleading. Therefore, the Court reminded companies that "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market."

Impact of *Matrixx*

Beyond clearly rejecting the proposition that the absence of statistically significant adverse events will insulate issuers from securities fraud claims based on the failure to disclose such events, the "something more" standard for materiality put forth by the Court for distinguishing routine adverse event reports from those requiring disclosure provides only limited guidance to issuers trying to satisfy their disclosure obligations. Issuers face myriad possible factual scenarios, and their disclosure obligations will continue to retain a certain amount of uncertainty.

But while the inherent uncertainty that accompanies materiality determinations is a necessary outgrowth of the inability to pre-analyze all potential factual circumstances, and the limits of bright-line rules, the implications of certain elements of the Court's decision should remind issuers that their actions and statements may be viewed in potentially unexpected ways and with 20/20 hindsight. For example:

- The Court seemed to view Matrixx's press releases as being exclusively directed at the securities markets, rather than at consumers, and focused on the stock price movement before and after the releases. Pharmaceutical companies are well aware of how consumer sentiment can shift rapidly in response to any public adverse event report, whether founded or unfounded, and will be motivated to respond promptly and publicly to such reports in a manner designed to preserve the product in the mind of the consumer. These companies will also need to be mindful that such statements could be viewed as market-directed.
- Quoting Matrixx's press releases within the text of the opinion, the Court disregarded statements of Matrixx's "belief" and its identification of basis therefor, choosing instead to characterize such statements as absolute statements of facts. Issuers should accordingly be conscious that the overall tone of their public statements may be more important than their otherwise careful wording.
- The Court relied on evidence gathered after the fact in support of the proposition that the disclosures were misleading when made. For example, the Court approvingly cites a 2009 warning letter from the FDA in support of the anosmia link, notwithstanding that the relevant class period was in 2003/2004. In addition, the Court notes that Matrixx made public statements regarding the safety of Zicam, although the panel Matrixx commission determined — two weeks after such disclosures — that insufficient scientific evidence existed to make such a determination.
- The Court concluded that Matrixx received "information that plausibly indicated a reliable causal link between Zicam and anosmia" based on reports by three medical professionals (two of whom were affiliates) of ten patient incidences, as well as four lawsuits, noting that it was unclear whether the lawsuits were from the same patients. The Court did not include any information in its decision regarding the number of Zicam users as a reference point, implying that the disclosure bar may be entirely unrelated to the number of users.

Given these observations, issuers would be well-advised to consider carefully what disclosures to make regarding adverse event reports, both in terms of securities law compliance as well as in terms of market reaction to their statements. We expect that arriving at the optimal balance will frequently be difficult.

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