Matrixx Initiatives, Inc. v. *Siracusano*: The Supreme Court Rejects "Bright-Line" Requirements for Alleging Materiality and Scienter in Securities Fraud Cases Against Pharmaceutical Manufacturers

In *Matrixx Initiatives, Inc.* v. *Siracusano*, No. 09-1156 (March 22, 2011), the Supreme Court addressed the pleading requirements for two key elements of securities fraud claims under Section 10(b) of the Securities Exchange Act and Rule 10b-5 in a case brought against a pharmaceutical company and its executives alleging a failure to disclose adverse event reports about the company's key product. Citing appellate court decisions from the First, Second, and Third Circuits, the defendants asserted that the complaint failed to state a claim for securities fraud. They alleged that the complaint failed to assert a *material* omission of fact because the number of purportedly concealed adverse events was not "statistically significant." The defendants also asserted that, for similar reasons, the complaint failed adequately to allege that the defendants acted with "scienter," the requisite intent to defraud.

In a unanimous opinion by Justice Sonia Sotomayor, the Supreme Court rejected defendants' proposed "bright-line" test that adverse event reports must be "statistically significant" in order to plead either a material omission or scienter. Instead, the Court held that, as to both the "materiality" and "scienter" elements, a careful evaluation of all of the complaint's factual allegations is required to determine their sufficiency. After undertaking such an evaluation, and considering the totality of the complaint's allegations (which included allegations of affirmative misrepresentations, as well as failure to disclose product liability litigation), the Court concluded the complaint adequately alleged both a material misrepresentation or omission and scienter.

While the holding of *Matrixx Initiatives* has significance for pharmaceutical and other companies, its impact should not be overstated. In rejecting a bright-line standard that would have provided pharmaceutical companies with a "safe harbor," the Court also stated that an alleged failure to disclose adverse events would not, by itself, automatically expose a company to potential securities fraud liability. Rather, there must be a fact-specific inquiry

Contacts

Scott B. Schreiber
+1 202.942.5672

Michael D. Trager
+1 202.942.6976

Daniel A. Kracov
+1 202.942.5120

Andrew T. Karron
+1 202.942.5335

Jeffrey L. Handwerker
+1 202.942.6103

that considers the source, content, and context of the adverse event reports and whether 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." Thus, for pharmaceutical companies and other issuers, the Court's discussion and application of its long-standing precedent on materiality, *Basic Inc.* v. *Levinson*, 485 U.S. 224 (1988), reaffirms that questions of materiality will turn on the specific facts alleged, as will determinations with respect to scienter.

Background and Proceedings Below

According to the complaint, Matrixx manufactured and sold Zicam Cold Remedy, an over-the-counter homeopathic drug product. Zicam was used to treat the common cold and accounted for approximately 70 percent of Matrixx's sales. The complaint alleged that, prior to the beginning of the class period, Matrixx and the individual defendants had received several reports that consumers had suffered a loss of their sense of smell (anosmia) after using Zicam. It also alleged that the active ingredient in Zicam was zinc gluconate, and that published medical studies linked another zinc compound, zinc sulfate, to anosmia.

The complaint alleged that, in light of this information, several statements issued by Matrixx during the proposed class period contained material misstatements, including:

- statements in October 2003, after an American Rhinologic Society presentation regarding reports of anosmia among Zicam users, that Matrixx was "'poised for growth in the upcoming cough and cold season'" and had "'very strong momentum;'"
- a November 2003 Form 10-Q which warned generally that product liability suits could adversely affect Matrixx's performance, but did not disclose the pending product liability litigation; and
- a Matrixx press release, issued in response to a January 30, 2004 Dow Jones report of an investigation by the US Food and Drug Administration (FDA) into complaints that Zicam could be causing anosmia, stating that any claims that Matrixx's products "cause anosmia (loss of smell) are completely unfounded and misleading," and that the safety and efficacy of zinc gluconate for treating common cold symptoms had been "well established" in two clinical trials.

The defendants moved to dismiss the complaint on the grounds that, because it failed to allege a statistically significant correlation between the use of Zicam and anosmia, none of the alleged misstatements or omissions were "material" under the securities laws. They also asserted that the complaint failed adequately to allege scienter because it did not allege that the Matrixx defendants disbelieved their statements about Zicam's safety or made suspicious stock sales. Citing a line of cases from the Second and Third Circuits involving the materiality of adverse event reports,[1] the District Court granted the motion on both grounds. The Ninth Circuit reversed, and the Supreme Court granted the Matrixx defendants' petition for certiorari.

The Supreme Court Rejects "Statistical Significance" as a Bright-Line Standard for Materiality

The Court began its analysis by reiterating the materiality standards it articulated more than two decades ago in *Basic Inc.* v. *Levinson*, 485 U.S. 224 (1988). Basic held that the requirement of a misleading statement or omission of material fact 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.'" [Basic, 485 U.S.] at 231-232 (quoting *TSC Industries, Inc.* v. *Northway, Inc.*, 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976)).

The Court noted that the Basic decision specifically rejected a bright-line rule for determining materiality, stating that "'[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive.'"

Following this reasoning, the Court rejected the defendants' argument that, as a matter of law, drug adverse event reports

1 *See*, e.g., *In re Carter-Wallace, Inc.*, 220 F.3d 36 (2d. Cir.1998); *Oran* v. *Stafford*, 226 F.3d 275, 284 (3d.Cir.2000). In the petition for certiorari, Matrixx also noted that the First Circuit had adopted the "statistical significance" test in *New Jersey Carpenters Pension & Annuity Funds* v. *Biogen IDEC Inc.*, 537F.3d 35, 48 (lst Cir. 2008).

cannot be material unless they are statistically significant. The Court concluded that, in some circumstances, a reasonable investor could consider relevant anecdotal adverse event reports that were not statistically significant. It observed that statistical significance is not a prerequisite for inferring a causal relationship, reasoning that (a) evidence sufficient to establish statistical significance may be unobtainable for rare (but serious) events, (b) the FDA and other medical professionals do not require statistically significant evidence to evaluate causation, and (c) courts may permit expert testimony on causation based on evidence that is not statistically significant. The Court concluded that "[g]iven that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well." Thus, "assessing the materiality of adverse event reports is a 'fact-specific' inquiry, *Basic*, 485 U.S. at 236, that requires consideration of the source, content and context of the reports."

Applying *Basic's* "total mix" standard, the Court had little difficulty in holding that the complaint adequately pleaded material misstatements and omissions. Stating that "this is not a case about a handful of anecdotal reports," the Court noted that allegations in the complaint concerning (a) the number and the nature of the adverse event reports, (b) the defendants' awareness of a presentation at a national medical conference linking the product to adverse events and of other studies suggesting that zinc could cause anosmia, (c) the reasonable inference from the complaint that Matrixx had not conducted its own studies but still issued statements that reports that Zicam caused anosmia were "completely unfounded and misleading," (d) the fact that Zicam accounted for 70 percent of Matrixx's sales, and (e) the fact that Matrixx had reported that it expected its revenues would increase between 50 and 80 percent, taken together, made it substantially likely that a "reasonable investor would have viewed this information as having significantly altered the 'total mix' of information made available."

The Supreme Court Rejects "Statistical Significance" as a Bright-Line Standard for Scienter

The Court next considered the Matrixx defendants' argument that because the plaintiffs did not allege that defendants knew that there was a "statistically significant" link between Zicam and anosmia, the complaint failed to allege that defendants acted with scienter. As required by the Private Securities Litigation Reform Act of 1995, the Court evaluated whether the complaint alleged with particularity facts "giving rise to a strong inference" of scienter. In doing so, it applied the standard announced in *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U. S. 308, 324 (2007), assessing whether "the inference of scienter [is] cogent and at least as compelling as any opposing inference."

Applying this standard, the Court held that "the inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that it simply thought the reports did not indicate anything meaningful about adverse reactions." In reaching this conclusion, the Court relied on allegations that Matrixx sought to initiate animal studies on zinc's safety, successfully acted to prevent public reference to Zicam by name at the American Rhinological Society conference, and issued a press release falsely suggesting that studies confirmed Zicam did not cause anosmia. The Court concluded that these allegations, "taken collectively, give rise to a 'cogent and compelling' inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market."

Significance and Implications of *Matrixx Initiatives*

As the Supreme Court's unanimous decision reflects, *Matrixx Initiatives* was, in certain respects, an easy case. In *Basic*, the seminal materiality case, the Supreme Court had expressly rejected a bright-line test. Moreover, since Matrixx contended that it was entitled to judgment as a matter of law based on a statistical significance requirement, the argument did not focus on other problematic factual allegations regarding the nature and context of the adverse event reports—in particular, the existence of studies credibly suggesting a causal link between Zicam and the adverse event and product liability claims. As the Court put it:

> This is not a case about a handful of anecdotal reports, as Matrixx suggests. Assuming the complaint's allegations to be true, as we must, Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia.

But if the result in *Matrixx Initiatives* is not particularly surprising, the opinion nevertheless warrants close attention and consideration. It does not offer clear guidance to pharmaceutical manufacturers specifically (or registrants generally) regarding the significance of isolated, statistically insignificant adverse event reports under the securities laws. In particular, given that many of these manufacturers must regularly submit adverse event reports to the FDA, and that most adverse event data are ultimately made available to the public through various sources, the decision provides little meaningful guidance as to when a pharmaceutical manufacturer must take the additional step of reporting such adverse events in its securities filings.

The Court's opinion recognizes that this is a problematic issue. After rejecting the defendants' proposed bright-line standard as inconsistent with *Basic*, the Court then immediately stated that it was not holding that the securities laws impose a mandatory requirement that "pharmaceutical manufacturers must disclose all reports of adverse events." Indeed, the Court specifically stated that,"[T]he 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 securities fraud pleading] standard. Something more is needed . . . .". The Court went on to add that Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information," and to suggest that "companies can control what they have to disclose" to avoid material misstatements or omissions "by controlling what they say to the market."

These statements undoubtedly will help pharmaceutical manufacturers accused of securities fraud refute mischaracterizations of *Matrixx Initiatives* as standing for the proposition that adverse event reports are per se material, and that the failure either to submit reports or to highlight such reports in a securities filing necessarily constitutes a violation of the securities laws. The "causal link" requirement should also provide some protection. However, in practice it may be very difficult for companies and their disclosure counsel to discern in real time when "something more" that triggers a disclosure obligation, such as a causal link, is present. Thus, *Matrixx Initiatives* leaves open the possibility that companies proceeding in good faith will still face the risk that the inadvertent nondisclosure of isolated, insignificant adverse event reports may, with the benefit of hindsight, be challenged as material even if they would not have triggered action, such as a labeling change, in the FDA context. That is an inherent flaw of the "total mix" test.

Yet, as the Court's opinion recognizes, it would be a mistake for companies to react to *Matrixx Initiatives* by assuming disclosure always is required. Rather, the prudent approach will continue to be consultation with disclosure and regulatory counsel to make informed disclosure decisions based on the specific facts at hand.

We hope that you have found this Advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

Scott B. Schreiber
Co-Chair, Securities Enforcement and Litigation Group
+1 202.942.5672
Scott.Schreiber@ aporter.com

Michael D. Trager
Co-Chair, Securities Enforcement and Litigation Group
+1 202.942.6976
Michael.Trager@ aporter.com

Daniel A. Kracov
Chair, FDA and Healthcare Group
+1 202.942.5120
Daniel.Kracov@aporter.com

Andrew T. Karron
+1 202.942.5335
Andrew.Karron@aporter.com

Jeffrey L. Handwerker
+1 202.942.6103
Jeffrey.Handwerker@ aporter.com