Supreme Court Rejects Bright-Line Test For Materiality in Rule 10b-5 Class Action With Respect to Adverse Event Reports

In *Matrixx Initiatives, Inc. et al. v. Siracusano, et al.*, decided on March 22, 2011, the Supreme Court addressed the circumstances under which adverse event reports ("AERs"), i.e., reports by users of a drug that they experienced an adverse medical event at some point during or following the use of that drug, will be considered "material" for purposes of Rule 10b-5 fraud claims under the Securities Exchange Act of 1934. In a unanimous decision, the Court held that, in assessing the materiality of AERs, a court must engage in a fact-specific inquiry that considers the "source, content, and context of the reports." In reaching this conclusion, the Court rejected a bright-line test that AERs are material only when, taken together, they provide "statistically significant" evidence that the drug caused the adverse event. Although the Court's decision is, generally speaking, simply a reaffirmation of its previous decision in *Basic v. Levinson* – the fount of the fact-specific test for materiality – it does offer some useful guidance to companies. With respect to the disclosure of AERs, the decision indicates that causation is critical to the materiality inquiry and that plaintiffs, at the very least, must allege facts that plausibly indicate a "reliable" causal link between the drug and the adverse effect. And, as a more general matter, the decision underscores the fact that a company can control what it has to disclose by controlling what it says in the market.

The defendant-petitioner in the case was Matrixx Initiatives Inc. ("Matrixx"), a pharmaceutical company that sells over-the-counter cold-remedy products. One of its main products is Zicam Cold Remedy, which, during the relevant time period, accounted for 70% of Matrixx's sales. From 1999 to 2004, Matrixx received several adverse event reports linking Zicam to "anosmia," the loss of smell. Most of these reports came from three medical professionals and researchers who had treated or studied patients who had developed anosmia after using Zicam. In reporting their results, two of these professionals further informed Matrixx of prior studies linking Zicam's key ingredient, zinc, to anosmia. As these reports were coming in, multiple plaintiffs filed product liability suits against the company, alleging that Zicam had damaged their sense of smell.

Matrixx allegedly largely ignored concerns over Zicam, while at the same time it publicly stated, among other things, that its annual revenues were poised to rise "up in excess of 50%." Later, when a report was published that the Food and Drug Administration ("FDA") was looking into the anosmia claims, Matrixx publicly stated that the anosmia claims were "completely unfounded and misleading." Matrixx, however, backpedaled from this statement after a nationally broadcast morning news program highlighted scientific findings linking Zicam to anosmia. Following the program's airing, Matrixx publicly stated that there was "insufficient scientific evidence" on whether Zicam affected the sense of smell.

In 2004, the Matrixx plaintiffs filed a Rule 10b-5 class action against Matrixx in federal district court in Arizona. They claimed that Matrixx's public statements about Zicam's safety and the company's statement about revenues were false and misleading because they omitted mention of the AERs. The district court dismissed the complaint. It held that, because the AERs, taken together, did not provide statistically significant evidence that Zicam caused anosmia, no reasonable investor would care to know about them. The Ninth Circuit reversed, holding that the district court erred in relying on the statistical significance test and that *Basic* required a "fact-specific inquiry." After engaging in this inquiry, the Court of Appeals held that the plaintiffs had sufficiently pled materiality.

The Supreme Court affirmed. It began its materiality analysis by restating *Basic*'s fact-specific test for materiality (i.e., an omitted fact is material where 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 then emphasized that *Basic* had rejected wooden approaches to materiality that designate certain facts or occurrences as dispositive in a given case. With that background in place, the Court swiftly dispatched of Matrixx's bright-line, "statistical significance" test, which the Court said would "artificially exclud[e]" information that "would otherwise be considered significant to the trading decision of a reasonable investor." With respect to assessing the materiality of AERs, the Court said that courts must engage in a "fact-specific inquiry" that considers the "source, content, and context of the reports." Although the Court focused primarily on materiality, it also stated that, under *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, the plaintiffs had adequately pled scienter. On this point, the Court found that the facts alleged gave rise to a strong inference that Matrixx withheld the AERs for fear that they would affect the market for their key product. This inference, the Court explained, was as compelling as an inference that Matrixx withheld the AERs because it thought they were meaningless.

Broadly framed, the decision reflects the Court's continued reluctance to adopt bright-line rules when it comes to materiality. Although this aspect of the decision underscores that early dismissal of a Rule 10b-5 claim on materiality grounds is difficult, the Court's application of the materiality test to the allegations in the case suggests that materiality arguments may in some cases prevail on a Rule 12(b)(6) motion. Citing to its *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal* decisions that bar conclusory pleading of allegations, the Court made clear that, while plaintiffs need not allege that the AERs offer statistically significant evidence that the drug caused the adverse event, they still must allege facts plausibly indicating a "reliable" causal link. The Court began by pointing to the fact that three medical professionals and researchers had informed Matrixx of a link between Zicam and anosmia and that two of the doctors had further presented their findings of a causal link to a national medical conference. But the Court did not hold that these allegations together sufficed to get the plaintiffs past a motion to dismiss. Rather, the Court went on to say that: "*Critically*, both Dr. Hirsch and Linschoten had also drawn Matrixx's attention to previous studies that had demonstrated a biological causal link between intranasal application of zinc and anosmia." At the very least, then, the Court's decision places the burden on plaintiffs to allege facts that, if taken as true, establish a reliable scientific foundation of causation.

Further, in the decision, the Court took care to emphasize that a company can exercise control over its disclosure obligations by controlling what it says in the market. The Court underscored the fact that Rule 10b-5 does not require companies to speak, but rather, requires companies that choose to speak to speak accurately. This point had particular resonance in the case, as Matrixx had not only forecasted very specific and optimistic increases in revenue after receiving the AERs, but had publicly dismissed the anosmia claims as "completely unfounded and misleading."

We note also one issue that the Court's decision did not address: the availability of a "loss-causation" defense to companies subject to a regulatory obligation to disclose AERs to the FDA under 21 U.S.C. § 379aa. As the United States conceded in its amicus brief on behalf of the plaintiffs, companies subject to this obligation could argue that the AERs have already been disclosed to the market via the FDA, calling into question the ability of plaintiffs to plead or prove loss causation. The Supreme Court's decision did not touch on this question because, during the class period, Matrixx was not subject to this regulation.

If you have any questions about this alert, please contact the Ropes & Gray attorney that usually advises you.