

March 25, 2011

U.S. SUPREME COURT DECIDES SCOPE OF MATERIALITY UNDER FEDERAL SECURITIES LAWS

To Our Clients and Friends:

On March 22, 2011, the United States Supreme Court issued a unanimous opinion affirming the Ninth Circuit's decision in *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009). The Court held that plaintiffs adequately pleaded materiality and scienter, stating a claim under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5, based on a pharmaceutical company's nondisclosure of adverse event reports, even though the reports were not alleged to be statistically significant. [*Matrixx Initiatives, Inc. v. Siracusano*](#), No. 09-1156, 563 U.S. ____ (2011).

The Supreme Court's decision resolves a split of authority between the Ninth Circuit and the First, Second, and Third Circuits, which previously had held that drug companies have no duty to disclose adverse event reports until those reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. *See, e.g., N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008); *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36, 41-42 (2d Cir. 2000); *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998); *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000).

Background of *Siracusano* Litigation

Plaintiffs alleged that Matrixx and three of its officers failed to disclose reports that its product, Zicam Cold Remedy, could cause anosmia, or loss of smell. The complaint alleged that, well before the class period, Matrixx knew of reports linking anosmia to Zicam use. For example, doctors were alleged to have told Matrixx that patients had developed the condition after using Zicam, and reported that "previous studies had demonstrated that intranasal application of zinc could be problematic." Slip Op. at 3. In addition, several products liability cases were filed just before and during the class period (many others were filed after the class period). Defendants nevertheless made certain allegedly false statements about Zicam, including that Zicam was "poised for growth in the upcoming cough and cold season" and that Matrixx had "very strong momentum." *Id.* at 4. While Matrixx discussed the risk of products liability litigation generally, it did not disclose that lawsuits had been filed against Matrixx for anosmia allegedly caused by Zicam. Nor did it reveal that patient complaints about anosmia had been brought to the Company's attention. *Id.* at 5.

Following these company statements, there were news reports that the FDA was investigating Zicam in light of the products liability suits. Plaintiffs alleged that Matrixx's stock price declined following the news reports. The Company issued a press release three days later stating that the assertions that "intranasal Zicam products cause anosmia . . . are completely unfounded and misleading," attacking the credibility of the reports and citing two studies of Zicam's safety and efficacy. *Id.* at 5-6.

Finally, *Good Morning America* broadcast a story about Zicam, reporting on the alleged link between Zicam and anosmia, and that lawsuits had been filed. Afterward the broadcast, Matrixx's stock price is

alleged to have "plummeted, falling from \$13.05 per share on February 5, 2004, to close at \$9.94 per share on February 6--a one-day drop of 23.8% on unusually heavy trading volume." *Id.* at 6. Matrixx assured the public that its products were manufactured according to FDA standards and that no study had linked anosmia and Zicam use. The company convened experts who determined that there was insufficient evidence to determine whether Zicam could cause anosmia. *Id.* at 6-7.

For additional background on the lower court decisions and the split of authority between the First, Second, Third, and Ninth Circuits, please see Gibson Dunn alert, "[U.S. Supreme Court to Decide the Scope of Materiality under Federal Securities Laws](#)" (July 15, 2010).

The Supreme Court's Decision

Materiality

To state a claim for securities fraud under Section 10(b), a plaintiff must show that the defendant made a statement that was "*misleading as to a material fact.*" Slip Op. at 9 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)). In *Siracusano*, the Supreme Court reaffirmed that the materiality requirement 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." *Id.* at 10 (quoting *Basic*, 485 U.S. at 231-32).

The Court reaffirmed *Basic*, and declined to adopt a bright-line rule that adverse event reports relating to a company's products are immaterial absent a statistically significant risk that the product is the cause of the adverse events. The Court held that such a rule would "artificially exclude[e]" information that would otherwise be considered significant to a reasonable investor's trading decision. *Id.* at 11 (quoting *Basic*, 485 U.S. at 236).

Rejecting Matrixx's argument that statistical significance is the only reliable indication of causation, the Court reasoned that statistically significant data is not always available (*e.g.*, when an adverse event is subtle or rare) and that, in any event, "[a] lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events." *Id.* at 12. The Court emphasized that the FDA does not limit the evidence considered for purposes of assessing causation to statistically significant data, but instead relies on a wide range of evidence and "sometimes acts on the basis of evidence that suggests, but does not prove, causation." *Id.* at 13. Given that medical professionals and regulators act based on evidence of causation that is not statistically significant, the court concluded that "in certain cases reasonable investors would as well." *Id.* at 15.

Importantly, the Court emphasized that its holding "does not mean that pharmaceutical manufacturers must disclose all reports of adverse events." *Id.* Rather, "[t]he question remains whether a *reasonable* investor would have viewed the nondisclosed information 'as having *significantly* altered the 'total mix' of information made available.'" *Id.* at 15-16 (quoting *Basic*, 485 U.S. at 232). The Court stated that the "mere existence" of adverse events reports will not satisfy this standard. *Id.* at 16. The Court's test requires a contextual, case-by-case inquiry as to whether a reasonable investor would have viewed adverse event reports as material even in the absence of statistically significant evidence. *Id.*

Applying this standard to the allegations against Matrixx, the Court held that plaintiffs adequately pleaded materiality. Accepting the complaint's allegations as true, the Court concluded that the "total mix of information" leads to the conclusion that plaintiffs had adequately pleaded materiality. Specifically, the Court noted: 1) the information provided to Matrixx by three medical experts relating information about more than 10 affected patients; 2) the allegation that a company official said that Matrixx had received additional reports of anosmia; 3) the existence of four product liability cases during the class period relating to nine different plaintiffs claiming that Zicam caused anosmia; and 4) the company knew that two researchers had presented findings to a national medical conference regarding a causal link between Zicam and anosmia. *Id.* at 17-18. Given that Zicam was Matrixx's most important product, it was substantially likely that a reasonable investor would have viewed this information "as having significantly altered the 'total mix' of information made available," and the complaint therefore adequately pleaded the requisite material misrepresentation or omission. *Id.* at 19.

Finally, the Court emphasized the rule that Section 10(b) and Rule 10b-5 do not create an affirmative duty to disclose material information. Rather, disclosure is required "only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* at 16 (quoting 17 C.F.R. § 240.10b-5(b)). Thus, "[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." *Id.* But Matrixx had announced that Zicam revenues were going to rise 50 and then 80 percent, that "the reports indicating that Zicam caused anosmia were 'completely unfounded and misleading' and that 'the safety and efficacy of [Zicam's active ingredient] for the treatment of symptoms related to the common cold have been well established.'" Slip. Op. at 19. In light of these statements, and the allegation that Matrixx did not have scientific evidence disproving the link between Zicam and anosmia, the Court held that defendants could not be silent about the reports they received about that possible link.

Scienter

To establish liability under Section 10(b) and Rule 10b-5, a plaintiff must show that the defendant acted with scienter. Moreover, under the PSLRA, a plaintiff is required to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Pursuant to the Supreme Court's decision in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007), a complaint adequately pleads scienter under the PSLRA, "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."

Applying these principles, the Court rejected Matrixx's proffered bright-line rule requiring an allegation of statistical significance to establish the requisite strong inference of scienter. Slip Op. at 21. According to the Court, the complaint's 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 instead because it understood their likely effect on the market. *Id.* at 22 (quoting *Tellabs*, 551 U.S. at 324). Because such inference was at least as compelling as any competing inference from the facts alleged, the Court held that plaintiffs adequately pleaded scienter under the PSLRA. *Id.*

Implications for Issuers

- Although every adverse event report may not necessarily require disclosure, issuers should be cautious in issuing categorical denials related to such reports (or related litigation). Indeed, the Court's decision in *Siracusano* emphasizes that any determination of materiality of information is necessarily a case-by-case determination highly dependent on the specific facts and context in question. *Reliance on the statistical insignificance of such reports or claims alone may not be sufficient.*
- If specific lawsuits are pending, or adverse event reports remain outstanding, issuers may need to include a specific discussion of such claims or adverse events; a general discussion about the risks of product liability claims may not suffice if, in the context of other relevant facts, omission of these claims or events would be viewed as significantly altering the total mix of information available.
- Issuers should consider Matrixx's holding along with FAS 5 when considering how to report the potential significance of lawsuits or other claims filed against the issuer. Legal and regulatory challenges to a product could be seen, taken together in context, as altering the "total mix" of information about the company even in the absence of statistically significant supporting evidence. *Again, reliance on the statistical insignificance of such claims alone may not be sufficient.*
- In making disclosures regarding litigation, issuers should be mindful of the fact that it is possible to comply technically with certain SEC reporting requirements (e.g., materiality thresholds of lawsuits based on damages sought, compared with company assets), but still omit material information that should have been disclosed.
- Because there is no bright-line rule for determining whether adverse event reports are "material," issuers should carefully consider the context of the reports and any related facts and circumstances, including considering whether additional investigation would be prudent to assess the merit and materiality of such reports and related claims, and formulate an appropriate response.
- Do not lose sight of the rule that affirmative statements to the market can create a duty to disclose information, even where there is not otherwise a duty to disclose that information. Issuers should take care, when making affirmative statements that are not required, about what additional disclosure obligations they may be creating for themselves.



Gibson, Dunn & Crutcher lawyers are available to assist in addressing any questions you may have regarding these issues. Please contact the Gibson Dunn lawyer with whom you work, the authors (Ethan Dettmer (415-393-8292, edettmer@gibsondunn.com), Sally J. Berens (650-849-5348, sberens@gibsondunn.com), or Benjamin M. Glickman (650-849-5343, bglickman@gibsondunn.com)), or any of the following members of the Securities Litigation Practice Group Steering Committee:

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