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REPORT

SECURITIES FRAUD PLEADINGS

Matrixx Litigation: Supreme Court Throws Out 'Statistical Significance' Standard for Pleading Securities Fraud

BY MARK P. GIMBEL AND DAVID B.H. MARTIN

On March 22, 2011, the U.S. Supreme Court issued its decision in the case of *Matrixx Initiatives Inc. v. Siracusano*, No. 09-1156, 563 U.S. _____, slip op. (2011), holding that a failure to disclose adverse event reports for a pharmaceutical product may be material, for purposes of a securities fraud claim, even if the reports are not statistically significant. The Court further held that it is not necessary to allege that undisclosed adverse event reports are statistically significant in order to adequately plead scienter. The Court's decision is significant in that it resolves a Circuit split and reverses the ''statistical significance'' standard adopted by the First, Second and Third Circuits in securities fraud cases based on alleged non-disclosures of reports of adverse drug effects.

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Background

To bring a securities fraud claim under Section 10(b) of the Securities Exchange Act of 1934 a plaintiff must plead not only that the defendant made a misrepresentation or omission but also that the misrepresentation or omission was *material—i.e.*, that ''there is a substantial likelihood that a reasonable shareholder would consider it important.'' *TSC Industries Inc. v. Northway Inc.*, 426 U.S. 438, 449 (1976).

In *In re Carter-Wallace Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998), the Second Circuit adopted a bright-line rule under which the failure to disclose reports of adverse drug effects will not be deemed material unless the reports are statistically significant. In a later decision, the Second Circuit explained that statistical significance bears not only on materiality, but also on the question of whether the defendant acted with scienter. If a defendant does not have reason to believe that reports of adverse drug events are statistically sig-

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nificant, then there is no reason to infer that the defendant intended to mislead investors by failing to disclose the reports. *See In re Carter-Wallace Inc. Securities Litigation*, 220 F.3d 36, 41-42 (2d Cir. 2000).

The Second Circuit's ''statistical significance'' standard was subsequently adopted, with some variation, by the First and Third Circuits. *See New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 6 CARE 890 (1st Cir. 2008); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000) (Alito J.). The validity of this rule was called into question, however, by the Ninth Circuit's decision in *Siracusano v. Matrixx Initiatives Inc.*, 585 F.3d 1167, 1179, 7 CARE 1316 (9th Cir. 2009), which rejected the statistical significance standard.

The Matrixx Litigation in the Lower Courts

In *Matrixx*, investors brought securities fraud claims against the health care products company Matrixx Initiatives Inc., alleging that it failed to disclose material information concerning its lead product, Zicam, a homeopathic cold remedy. The complaints alleged that the company misled investors by projecting substantial revenue increases and representing that Zicam was positioned for growth while failing to disclose a variety of facts including reports that users of the cold remedy had experienced anosmia—the loss of the sense of smell. *Id.* at 1171-77. Following a Feb. 2, 2004, report on *Good Morning America* regarding the potential link between Zicam and anosmia, the price of Matrixx common stock plummeted, leading to the filing of securities fraud claims. *Id.* at 1175.

Relying on *Carter-Wallace* and its progeny, the district court dismissed the plaintiffs' claims, holding that Matrixx had no duty to disclose reports that users of Zicam experienced anosmia absent statistically significant evidence that Zicam caused the condition. The court reasoned that without ''a statistically significant correlation between the use of Zicam and anosmia,'' the failure to disclose the reports was not a ''material omission.'' *Siracusano v. Matrixx Initiatives Inc.*, 2005 WL 3970117, at *7 (D. Ariz. Dec. 15, 2005). It further held that the plaintiffs had failed to allege facts giving rise to a strong inference of scienter.

On appeal, the Ninth Circuit reversed, rejecting the statistical significance standard and holding that the district court should not have decided the issue of materiality as a matter of law. The court expressed the view that ''the statistical significance standard . . . is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of facts.'' *Matrixx*, 585 F.3d at 1183. It also reversed the district court's ruling as to scienter, holding that the defendant's alleged failure to disclose adverse event reports was an ''extreme departure from the standards of ordinary care'' that was sufficient to give rise to a strong inference of scienter. *Id.* at 1180-81 (internal citation and quotation marks omitted).

The Supreme Court's Ruling

The Supreme Court unanimously affirmed the Ninth Circuit's decision. In an opinion written by Justice Sonia M. Sotomayor, the Court rejected the defendant's argument that it should adopt a bright-line rule under which reports of adverse events linked to pharmaceutical products ''cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product is in fact causing the events.'' *Matrixx*, 563 U.S. ____, slip op. at 11. The Court reasoned that such a categorical standard would be inconsistent with its decision in *Basic v. Levinson*, which rejected bright-line rules in favor of a fact-specific inquiry in which the materiality requirement is satisfied 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.' '' *Id.* at 10 (2011) (quoting *Basic v. Levinson*, 485 U.S. 224, 231-32 (1988) (internal citation and quotation marks omitted)).

In rejecting the proposed bright-line rule, the Court noted that medical professionals and regulators, including the FDA, rely on evidence that is not statistically significant to assess risk and take regulatory action. ''Given 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.'' *Id.* at 15. ''This is not to say that statistical significance (or the lack thereof) is irrelevant—only that it is not dispositive of every case.'' *Id.*

The Court also rejected the defendant's argument that the complaint failed to plead scienter, holding that the ''proposed bright-line rule requiring an allegation of statistical significance to establish a strong inference of scienter is just as flawed as [the defendant's] approach to materiality.'' *Id.* at 21. Scienter was adequately pleaded, because the complaint alleged facts that, ''taken collectively,'' gave rise to a '' 'cogent and compelling' inference that Matrixx elected not to disclose the reports of adverse events not because it believed

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they were meaningless but because it understood their likely effect on the market.'' *Id.* at 22 (quoting *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323, 24 (2007)).

Implications

The Supreme Court's decision will make it more difficult to obtain the dismissal of securities fraud claims on the pleadings in cases based on allegations of failure to disclose reports of adverse drug effects. In the absence of a bright-line rule, it may also be more difficult for pharmaceutical companies to determine when to disclose adverse event reports.

Importantly, as the Supreme Court was careful to note, the *Matrixx* decision "does not mean that pharmaceutical manufacturers must disclose all reports of adverse events."

It would be a mistake, however, to read too much into the *Matrixx* decision. In fact, for companies and their disclosure committees and advisors, the decision resolves a tension that had existed between the bright-line rule of statistical significance and seminal teachings, such as *Basic v. Levinson* and *TSC Industries Inc. v. Northway Inc.*, which avoid bright-line rules in favor of a holistic examination of the total mix of information available. In this regard, *Matrixx* also squares with parallels under the disclosure program of the Securities and Exchange Commission, which have long reminded registrants of the dangers of quantitative rules of thumb in assessing financial materiality and provided guidance on the need to consider qualitative materiality in the disclosure of risks and known uncertainties. *See, e.g.*, SEC Staff Accounting Bulletin No. 99 (Aug. 13, 1999) and *Commission Guidance Regarding Disclosure Related to Climate Change,* Rel. No. 33-9106 (Feb. 2, 2010).

Importantly, as the Supreme Court was careful to note, the *Matrixx* decision ''does not mean that pharmaceutical manufacturers must disclose all reports of adverse events.'' *Id.* at 15. Nor does it mean that the concept of statistical significance is irrelevant in assessing materiality. *Id.* Assessing the materiality of adverse event reports is a fact-specific inquiry that requires the consideration of numerous factors, including not only statistical significance but the ''source, content, and context of the reports.'' *Id.* Moreover, as the Court emphasized, it remains the rule that:

> § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading. Even 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. at 16 (internal citations and quotation marks omitted).

These important limitations on the Court's holding underscore that, while the *Matrixx* decision unquestionably will change the pleading dynamics in securities fraud cases, it leaves untouched, but helpfully clarified, the fundamental precepts of materiality assessments in the context of securities disclosures of public companies.