

Supreme Court to Review Statistical Significance Standards in Connection with § 10b-5 Claims

On June 14, 2010, the U.S. Supreme Court agreed to decide whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on a pharmaceutical company's non-disclosure of adverse event reports, even when those reports are not alleged to be statistically significant.

Background

The case, *Matrixx Initiatives, Inc. v. Siracusano* (June 14, 2010) (No. 09 -1156), involved a class action suit against Matrixx and three of its executives under § 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder, in which the plaintiffs alleged that Matrixx had failed to disclose material information regarding its Zicam[®] Cold Remedy, specifically that Zicam caused a condition called amnesia (a loss of the sense of smell) in its users, and that the failure to disclose this information inflated the price of Matrixx's common stock during the class period. During the period in question, Matrixx had received approximately 12 reports of user amnesia and was named in four Zicam-related lawsuits involving nine plaintiffs who allegedly suffered from amnesia. Matrixx's public filings and statements were generally positive during this period and downplayed the significance of the Zicam complaints, including allegations in an article in *The Wall Street Journal* that the FDA was investigating whether the Zicam Cold Remedy caused this condition.

Ninth Circuit Decision

The Federal District Court in Arizona dismissed the complaint, reasoning that the allegations of user complaints were not material as a matter of law because they were not "statistically significant." The Ninth Circuit reversed, stating that the District Court's reliance on the statistical significance standard to conclude that plaintiffs had failed to establish materiality was inconsistent with the Supreme Court's rejection of bright line rules, and its emphasis on having materiality determined by the trier of fact. See *Siracusano v. Matrixx Initiatives, Inc.*, 525 F.3d 1167 (9th Cir. 2009).

Second Circuit Approach

The defendants argued that this ruling was inconsistent with the Second Circuit's decision in *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000), which the defendants cited as the standard for determining when allegations of undisclosed adverse event reports can satisfy the materiality requirement under § 10(b) and Rule 10b-5. The District Court reasoned that in *Carter-Wallace*, the Second Circuit held that no claim can be based on the nondisclosure of adverse event reports "unless such reports provide reliable statistically significant information that a drug is unsafe." Applying that standard, the District Court concluded that respondents had alleged "no data as to the reliability and accuracy of the user complaints," and that "[e]ven if there were data as to the reliability" of the complaints, "12 user complaints is not statistically significant."

The defendants also argued that both the First and the Third Circuits have adopted the Second Circuit's statistical significance test. The Third Circuit held that "drug companies need not disclose isolated reports

of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by — rather than randomly associated with — use of the drugs.” *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157). Because the reports at issue were not “statistically significant,” the court held that their nondisclosure was not “materially misleading.” *Id.*

Similarly, the defendants argued that the First Circuit has adopted the statistical significance test. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 46 (1st Cir. 2008), the First Circuit rejected a plaintiff’s § 10(b) claim that was based on nondisclosure of adverse event reports. The court explained that there was “no basis to conclude that these results ... were statistically significant,” and that “the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.” *Id.* at 50, 53 (quoting *Carter-Wallace II*, 220 F.3d at 41).

Plaintiffs responded that there was no real split among the Courts of Appeals, and that the statistical significance test in the First and Second Circuit cases cited by plaintiffs was in the context of establishing scienter, not materiality, and that the Third Circuit case was decided on other materiality grounds. The Supreme Court granted *certiorari* to resolve the question, and will decide the case in the term beginning in October 2010.

Significance of the Supreme Court’s Decision

The choice between the Ninth Circuit approach and that of the Second Circuit could have a dramatic impact on pharmaceutical companies. The Second Circuit’s approach affords pharmaceutical companies some predictability as to the timing and nature of disclosure required by negative information. If the Supreme Court adopts the Ninth Circuit’s approach, pharmaceutical companies may be obligated to disclose negative results based on much less information. Adoption of the Ninth Circuit’s approach would also make it much less likely that this type of securities fraud claim could be eliminated on a motion to dismiss, and would thus generally increase the costs and risks of defending them.

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