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# The Supreme Court Considers the Materiality Requirement in the Context of Drug Companies' Disclosure of Adverse Event Reports

*January 11, 2011*

The Supreme Court heard oral arguments yesterday in *Matrixx Initiatives, Inc. v. Siracusano,* No. 09-1156, a securities fraud case in which the Court is expected to address the question of whether pharmaceutical company Matrixx Initiatives, Inc. ("Matrixx") was required to disclose reports of adverse events following the use of its cold remedy product even though the reports are not alleged by the plaintiffs to have been statistically significant. Although the question presented is limited, in deciding this case, the Court may provide more general insight into the analysis lower courts should employ in evaluating the materiality of alleged misstatements or omissions at the motion to dismiss stage.

## BACKGROUND

The *Siracusano* case relates to alleged misstatements and omissions by Matrixx regarding its main product: Zicam Cold Remedy, a homeopathic remedy used to reduce the severity and duration of the common cold. Prior to the events at issue in the case, Matrixx studied the intranasal application of the active ingredient in Zicam, zinc gluconate, through two published double-blind, placebo-controlled, randomized clinical studies. Matrixx concluded based on both studies that: "[t]he overall incidence of adverse events associated with zinc gluconate treatment was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets." Br. for Pet'rs at 5.

The plaintiffs allege that, beginning in December 1999, Matrixx started receiving isolated reports that certain consumers experienced the loss of smell, or anosmia, following the use of Zicam. Specifically, the plaintiffs allege: (1) in December 1999, Matrixx was informed by Dr. Alan Hirsch that he was aware of "at least one" consumer who complained of anosmia following the use of Zicam; (2) in September 2002, defendant Timothy Clarot, Matrixx's Vice President and Director of Research and Development, spoke with Dr. Miriam Linschoten of the University of Colorado Health Services Center after one of Dr. Linschoten's patients complained to Matrixx of anosmia; and (3) in September 2003, Dr. Bruce Jafek of the Department of Otolaryngology at the University of Colorado School of Medicine prepared a presentation with Dr. Linschoten and another colleague reporting ten claims of anosmia following the use of Zicam.

On January 30, 2004, the *Dow Jones Newswire* reported that three lawsuits had been filed against Matrixx as a result of complaints that Zicam caused anosmia, allegedly causing a dip in the price of Matrixx's shares. On February 2, 2004, Matrixx issued a press release,

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contending that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading." Br. for Pet'rs at 8. On February 6, 2004, Dr. Bruce Jafek affirmatively stated on a *Good Morning America* segment that Zicam caused anosmia. Matrixx issued another press release that day, reiterating the statement that Zicam does not cause anosmia. Matrixx's stock price dropped from the previous day's close of $13.04 to $9.94. On February 27, 2004, in a Form 8-K filing with the SEC, Matrixx stated that it had convened a "two-day meeting of physicians and scientists to review current information on smell disorders" in response to the recent claims that Zicam caused anosmia and that the panel found "insufficient scientific evidence at [that] time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." Br. of Resp'ts at 15.

On April 29, 2004, plaintiffs brought suit against Matrixx and certain of its officers in the District of Arizona, alleging that Matrixx's misstatements and omissions of the adverse events purportedly caused by Zicam caused the company's statements about business growth and Zicam safety to be false and misleading. The plaintiffs claim that, during the Class Period (October 23, 2003 to February 6, 2004), Matrixx falsely and misleadingly touted the growth of its business and the success of Zicam by failing to disclose the purported claims by certain users that Zicam caused anosmia. The plaintiffs also claim that Matrixx's misstatements and omissions were made with scienter because, since at least September 2003, Matrixx was aware that numerous users had experienced anosmia in connection with the use of Zicam.

Matrixx moved to dismiss the complaint, arguing that the plaintiffs failed to plead sufficiently the elements of materiality and scienter. This argument was supported by decisions of the Second and Third Circuits that adverse event reports need not be disclosed until there is "statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drug[]." *Oran v. Stafford*, 226 F. 3d 275, 284 (3d Cir. 2000); *see In re Carter-Wallace, Inc. Secs. Litig.* (*Carter Wallace II*), 220 F. 3d 35 (2d Cir. 2000). Relying upon *Carter-Wallace II*, the district court dismissed the case due to the plaintiffs' failure to show materiality of the alleged misstatements and/or omissions, holding that "there is no data as to the reliability and accuracy of the user complaints" and "[e]ven if there were . . ., the Court finds 12 user complaints is not statistically significant." No. CV 04 0886 PHX MHM, 2005 WL 3970117, at *7 (Dec. 15, 2005 D. Ariz.). The district court also held that the plaintiffs failed to allege facts showing a strong inference of scienter because: "[i]t is just as reasonable to infer, Defendant's were appropriately protecting Zicam's good name and marketability." *Id*. at *8.

On appeal, the United States Court of Appeals for the Ninth Circuit reversed and remanded, concluding that "the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality." 585 F. 3d 1167, 1178 (9th Cir. 2009). The Ninth Circuit held that "the district court made a decision that should have been left to the trier of fact." *Id*. at 1179. The Ninth Circuit also found that, "[b]y the time of the February 2, 2004 press conference, a strong inference can be drawn that Appellees knew that the statements alleging a link between Zicam and anosmia were not 'completely unfounded and misleading.'" *Id*. at 1182. Accordingly, the Court of Appeals concluded: "[T]he inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently." *Id*. at 1183.

**SUMMARY OF THE ARGUMENT**

In front of the Supreme Court yesterday, Defendant-Petitioner Matrixx argued against the required disclosure of adverse event reports, maintaining that all pharmaceutical companies receive anecdotal reports of alleged adverse effects following the use of their drugs and that these incidents do not establish any reliable facts about the drug's performance or safety.

Justice Ginsburg first observed that, although plaintiffs here at most were able to identify twenty three complaints of adverse events, "[the plaintiffs] might have been able through discovery to find that there were many more." Following Matrixx's contention that the plaintiffs had not alleged that they could find a statistically significant relationship between the use of Zicam and anosmia, Justice Ginsburg stated: "But why shouldn't that determination be deferred until there's discovery, and then we can know how many reports there really were?"

Justice Alito then questioned: "Can there be some situations in which statistically significant evidence would not be necessary?" Although Matrixx's counsel acknowledged that "there are a very narrow, limited number of circumstances under which a claim can be pled absent statistically significant evidence," such as under the Bradford-Hill criteria, he argued that the plaintiffs failed to allege the existence of any such criteria here. Justice Scalia observed that, in addition to the adverse event reports, the complaint refers to a study by the American Rhinologic Society asserting a connection between the use of Zicam and anosmia.

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*CHIEF JUSTICE ROBERTS*

Rather than "talking about who is right or wrong about the connection between Matrixx and anosmia," Chief Justice Roberts commented: "I'm an investor in Matrixx; I worry whether my stock price is going to go down. You can have some psychic come out and say 'Zicam is going to cause a disease' with no support whatsoever, but if it causes the stock to go down 20 percent, it seems to me that's material."

Justice Breyer was unsure what was "within the range of expectation of drug companies as part of the normal course of business," and asked how courts should determine whether or not particular adverse event reports "arise above the background noise of a drug company." After Matrixx argued for the statistical significance test employed by the Second Circuit in *Carter-Wallace*, Justice Breyer commented: "Oh, no, it can't be. . . . So we could get the greatest doctor in the world and he has dozens of theories, and the theories are very sound and all that fits in here is an allegation he now has learned that it's the free zinc ion that counts. And that could be devastating to a drug even though there isn't one person yet who has been hurt. So I can't see how we can say this statistical evidence always works or always doesn't work."

*". . . I can't see how we can say this statistical evidence always works or always doesn't work."*

*JUSTICE BREYER*

Plaintiffs-Respondents argued that materiality should be judged based on the total mix of information available to investors, and that Matrixx seeks a significant change to the Court's approach to materiality by offering the bright-line standard of statistical significance.

Justice Kennedy questioned: "At some point do we look at scienter and then go back from that to whether or not it's material . . . . Or do we do this with two isolated boxes: one, materiality, two, scienter, and we don't mix the analyses?" The plaintiffs responded that they are "both analytically distinct and related" and that the "Court has announced separate tests."

Justice Breyer asked the plaintiffs: "[H]ow would you write some words that will put a disclosure obligation such that it's not going to be overkill and it is going to get incidents that rise above the background noise . . . ?" The plaintiffs referred to: ". . . the language in *Basic* which says the total mix of information is what has long standing been the test for materiality under this Court's cases."

Chief Justice Roberts asked: "So what protection is there at the summary judgment stage in response to allegations?" The plaintiffs again referred to *Basic*, noting that "this Court and many courts have always looked at a reasonable person's standard in making all sorts of these fine judgments about the importance of particular information." Justice Scalia commented: "[I]t seems to me ridiculous to . . . hold companies to . . . irrational standards . . . . [Y]ou are saying well, the reasonable investor takes account of the irrationality. I don't think that's what we meant in . . . *Basic*."

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*JUSTICE SCALIA*

The United States, the Securities and Exchange Commission, and the Department of Health and Human Services, represented by the Solicitor General's Office, argued in support of the plaintiffs. The Government emphasized that "this Court's precedents have instructed that information is material for securities fraud purposes if a reasonable investor would have viewed it as having meaningfully altered the total mix of information." The Government also maintained that, if a company were to issue statements regarding its projected future success, it would also need to disclose that, if known to it, ten percent of the company's consumer base intended to boycott the company's products, even if the basis for the boycott were ridiculous and untrue. The Government urged "due deference" to the SEC's views on the application of the materiality standard.

On rebuttal, Matrixx focused on scienter, arguing that the plaintiffs failed to allege facts "sufficient to establish Matrixx actually knew that Zicam causes anosmia and yet willfully refused to tell investors that fact . . . ."

## IMPLICATIONS

Specifically at issue here is whether pharmaceutical companies must disclose reports of adverse events following the use of their products even though the reports are not alleged by the plaintiffs to have been statistically significant. Matrixx has argued that the Ninth Circuit's decision allowing the plaintiffs' claims to proceed based on the allegations here conflicts with decisions from the Second and Third Circuits holding that pharmaceutical companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events in fact may be caused by the drug's use. If the Ninth Circuit's approach is approved, pharmaceutical companies will need to disclose negative reports about their products regardless of the reliability of the information, which could result in a welter of anecdotal information of limited value to investors, medical professionals, and patients. The Court is expected to resolve this split and to provide guidance to pharmaceutical companies as to when adverse events experienced following use of their drugs must be reported. More broadly, the *Matrixx* case might present the Court with an opportunity to consider the general pleading standards applicable to materiality and scienter in the securities fraud context.

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