Under SEC Rule 10b-5, Must a Plaintiff Allege That a Stock Issuer's Omissions Were Statistically Significant?

CASE AT A GLANCE

Plaintiffs allege that Matrixx Initiatives, Inc. violated Section 10(b) of the Securities and Exchange Act by failing to disclose adverse medical events and lawsuits associated with the use of Zicam, a homeopathic cold remedy. Physicians had notified Matrixx about a dozen consumers who developed anosmia—the loss of smell—immediately after using Zicam. In addition, a handful of the millions of Zicam users had sued Matrixx. Matrixx argues it was not required to disclose these adverse medical reactions because they were not statistically significant.

Matrixx Initiatives v. Siracusano
Docket No. 09-1156

Argument Date: January 10, 2011
From: The Ninth Circuit

by Jayne Zanglein and Matthew Sullivan
Western Carolina University, Cullowhee, NC

ISSUE

To meet the materiality requirement of SEC Rule 10b-5, must a plaintiff who claims that a stock issuer failed to disclose patient complaints of serious medical side effects allege that the incidents of adverse medical events were statistically significant?

FACTS

In this class action, shareholders allege that Matrixx Initiatives, Inc. violated Rule 10b-5 of the Securities and Exchange Act (SEA) by issuing materially false and misleading statements concerning its product Zicam, which represents 70 percent of Matrixx's sales. Shareholders allege that Matrixx failed to disclose that Zicam nasal spray/gel caused anosmia (the loss of the sense of smell) in numerous users. Shareholders who purchased Matrixx shares between October 22, 2003, and February 6, 2004 (class period), claim that although Matrixx disclosed potential lawsuits in its securities filings, the company failed to warn them of pending lawsuits and adverse medical reports. On February 6, when the safety of Zicam was questioned on *Good Morning America,* stock price plummeted from $13.04 to $9.94.

Zicam is a homeopathic cold relief medicine made with zinc *gluconate*. In 1999, neurologist Dr. Alan Hirsch noticed that a group of his patients who used Zicam nasal gel had developed anosmia. He reported the side effect to Matrixx and informed the company that previous studies in the 1930s linked intranasal application of zinc *sulfate* to anosmia. Dr. Hirsch offered to conduct a clinical study for Matrixx to determine if zinc sulfate had the same side effects as zinc gluconate, but Matrixx declined.

In September 2002, Matrixx's Vice President called Dr. Miriam Linschoten at the University of Colorado about one of her patients who had complained to Matrixx of loss of smell. When Matrixx's VP said that Matrixx had not conducted clinical studies of Zicam, Dr. Linschoten told him that previous studies had linked zinc sulfate to the loss of smell. Matrixx requested that Dr. Linschoten conduct animal studies on the effect of Zicam, but she declined because she did not work with animal subjects.

Later that month, Dr. Linschoten and her colleague, Dr. Bruce Jafek of the University of Colorado School of Medicine, made a poster presentation for the American Rhinologic Society meeting on the link between use of Zicam nasal spray and anosmia. The presentation featured a patient who, upon using Zicam spray, immediately suffered from severe nasal burning and loss of smell. The research identified nine other Zicam users who suffered from anosmia. Dr. Jafek rejected the possibility that the common cold had caused anosmia. Although a cold may result in anosmia, it typically occurs after a severe upper respiratory infection, which was not present in the users. This conclusion was also supported by complaints of immediate and several nasal burning following application of Zicam.

The doctors sent Matrixx an abstract of the poster presentation in advance of the session. Matrixx forbade them from using the names of Matrixx or Zicam in the presentation. Dr. Jafek complied.

On October 14, 2003, two patients filed suit against Matrixx alleging that Zicam caused anosmia. During the class period, eight additional consumers sued Matrixx for anosmia. On October 22, 2003, Matrixx issued a press release "indicating net sales increased by 164 percent by the third quarter of 2002 and stating 'the Zicam brand is poised for growth in the upcoming cough and cold season' and the Zicam brand is relied on 'as an efficacious product.'" *Siracusano v. Matrixx Initiatives, Inc.,* 2005 WL 3970117, at *1 (D. Ariz., Dec. 15, 2005). In

a quarterly report dated November 12, 2003, Matrixx repeated these favorable projections and reported on two clinical trials that had been conducted with no reports of anosmia. Matrixx tempered these positive reports with the disclaimer, "We may incur significant costs resulting from product liability claims."

On January 30, 2004, the *Dow Jones Wire* reported that three product liability suits linking Zicam to anosmia had been filed against Matrixx. A few days later, a Matrixx representative stated that "statements alleging intranasal Zicam products cause anosmia are completely unfounded and misleading." On February 6, 2004, *Good Morning America* featured Dr. Jafek's study, which linked use of Zicam to anosmia. Matrixx immediately issued another press release reaffirming Zicam's safety. Matrixx stock consequently plummeted by 23.8 percent.

A few weeks later, Matrixx filed a report with the Securities Exchange Commission (SEC) stating that review by a panel of doctors had concluded that there was "insufficient evidence to determine whether zinc gluconate affected the sense of smell."

Zicam users continued to complain of anosmia and lawyers continued to file lawsuits alleging that Zicam caused anosmia. By April 2004, Dr. Jafek had evaluated over 100 cases of anosmia and Dr. Linschoten estimated that she had treated 65 Zicam users who suffered from anosmia. Five years later, the Food and Drug Administration (FDA) issued a warning letter to Matrixx. Matrixx eventually recalled Zicam nasal spray and gel.

To state a securities fraud claim under Section 10(b) of the Securities and Exchange Act, shareholders must allege that Matrixx intentionally misrepresented or omitted a material fact in connection with the purchase or sale of a security. The shareholders here contend that Matrixx knew Zicam's risk, but continued to make positive statements regarding Matrixx's growth and Zicam's safety in violation of Section 10(b). The shareholders further argue that Matrixx knew or should have known Zicam was not safe due to the University of Colorado study and the product liability lawsuits.

Matrixx moved to dismiss the shareholders' case for lack of scienter and materiality. Matrixx argued that scienter was missing because it reasonably believed that the common cold caused the anosmia rather than Zicam; therefore, there was no intent to defraud. Matrixx also claimed the incidence rate of anosmia was so low as to be statistically insignificant and therefore immaterial.

The district court agreed with Matrixx and ruled that the shareholders did not assert an omission of a material fact. According to the district court, "adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe." The court further held that "Even if there were data as to the reliability, the Court finds 12 user complaints is not statistically significant. While the Complaint cites to 165 other complaints, it fails to allege those user complaints were within the class period or that Defendants had any knowledge of the complaints."

In general, to prove scienter, shareholders must "state with particularity facts giving rise to a strong inference that the defendant acted" with deliberate recklessness. If a "forward-looking statement" is involved, the court requires proof of actual knowledge. According to the district court, the shareholders also failed here: "… the Complaint fails to allege any motive or state of mind with relation to the alleged omissions." The court rejected the plaintiffs' argument that defendant's refusal to allow Dr. Jafek permission to Zicam's name in his presentation was evidence of scienter. The court further held that "It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability." The district court granted Matrixx's motion to dismiss the complaint. Plaintiffs appealed.

The Ninth Circuit reversed and remanded the district court's decision. The Ninth Circuit held that the district court should have allowed the jury to decide whether there was enough statistical significance to determine materiality. *Siracusano v. Matrixx,* 585 F.3d 1167, 1179 (9th Cir. 2009). Statistical significance cannot be determined as a matter of law, but instead is a question of fact. A fact, according to the Ninth Circuit, is "material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote." (quoting *TSC Indus., Inc. v. Northway, Inc.,* 426 U.S. 438, 449 (1976)). The Ninth Circuit concluded that the plaintiffs had sufficiently alleged materiality.

In coming to this conclusion, the Ninth Circuit defined *reckless* as "a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." (quoting *In re Silicon Graphics Inc. Sec. Litig.,* 183 F.3d 970, 976 (9th Cir. 1999)). The Ninth Circuit held that, based on the limited facts presented to the district court, it was just as likely that Matrixx was reckless in withholding information as that Matrixx withheld the information for innocent reasons. Therefore, the Ninth Circuit reversed the district court.

Matrixx filed a petition for certiorari.

CASE ANALYSIS

The Supreme Court has held that a fact is material if there is "a substantial likelihood that a reasonable investor would view it as 'significantly alter[ing] the total mix of information made available.'" Matrixx argues because Zicam was a homeopathic over-the-counter (OTC) remedy, the FDA did not mandate the submission of adverse event reports (AERs) to notify them of adverse reactions to the drug. Even if adverse event reports were mandatory, such reports are not material because a reasonable investor would not base investment decisions on them. Matrixx claims it had no duty to report AERs during the class period. It was not until 2006 that the FDA required manufacturers of OTC drugs to report severe AERs. The FDA defines an adverse event as any "adverse event associated with the use of a drug in humans, whether or not considered drug related." Matrixx describes AERs as "uncontrolled, unconfirmed multi-layer hearsay." Shareholders respond that all information about adverse drug reactions is material, even if the FDA does not require the reporting of AERs.

Matrixx contends that if the Supreme Court were to adopt a rule that considers AERs to be material, companies would feel compelled to disclose every report, thereby flooding the market with useless and misleading information that will undermine reasonable investment

decision making. Instead, "the reasonable investor will be fully aware that the FDA receives hundreds of thousands of AERs every year… and that neither the FDA nor courts treat those AERs as reliable indicators of a causal association between use of the drug and the reported adverse event." Forcing companies to disclose all AERs might obscure information that might be genuinely useful to an investor. According to Matrixx, the role of the materiality requirement is to filter out insignificant information investors would find useless such as AERs. Too much information is just as dangerous as too little information "because genuinely material information becomes hidden in plain sight." Matrixx contends that "AERs can be material only when they reflect a scientifically reliable basis for inferring a potential causal link between product use and the adverse event." Because the typical investor is not a scientist, [s]he "cannot be expected to sift significant from insignificant scientific data with ease." Matrixx claims that if investors are presented with information that they don't understand, and in a large amount, the investor may sell a security too soon or too late.

Matrixx further argues that the shareholders' complaint lists only 23 anosmia AERs and some of those AERs might be duplicates. Matrixx emphasizes that the 23 AERs were received over four years, when Matrixx sold millions of units of Zicam. Matrixx describes this as a "trivially minuscule … incident rate," especially when compared to the "known incident rate of anosmia in … the population of people *who have colds,* and thus take remedies like Zicam." Matrixx contends that the shareholders failed to take into consideration that some of the 23 cases of anosmia could have been caused from the underlying condition and not Zicam.

Shareholders claim that Matrixx knew Zicam was dangerous and intentionally withheld the information from investors. Shareholders contend that in 1999, Dr. Hirsch had found a causal link between users of Zicam and anosmia and reported it to Matrixx. A reasonable investor would have been concerned about this connection, particularly in light of the studies dating back to the 1930s detailing a connection between zinc and anosmia.

Shareholders further claim that Matrixx denied the causal link between Zicam and anosmia for three reasons: the costs associated with product liability suits, possible future FDA enforcement, and significantly reduced Zicam sales. According to the shareholders, such motives demonstrate the materiality of the causal link: Matrixx wouldn't have been so concerned with denying the link if they didn't think it would hurt sales, and therefore, the information was important to investors. Shareholders emphasize that the potential for drastically reduced sales is especially important: consumers would not buy a cold remedy that could lead to a problem far more serious than the cold itself. Furthermore, the 2009 FDA's warning letter tends to corroborate shareholders' claim that an investor would consider the adverse medical effects to be material in making an investment decision.

On February 2, 2004, after reports were published about the link between Zicam and anosmia, Matrixx continued to claim that Zicam was safe and that the statements were "completely unfounded and misleading." However, one month later Matrixx conceded that "insufficient scientific evidence [exists] at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." Shareholders contend that this proves that Matrixx made materially misleading statements, especially in light of the "sparse and cursory" clinical tests conducted on Zicam. In addition, shareholders argue that Matrixx's reversal on the issue of scientific studies shows scienter. Moreover, shareholders contend that Matrixx acted with scienter because it invited Dr. Linschoten to participate in animal studies.

Shareholders further reject Matrixx's contention that too much information will confuse investors. The shareholders argue that, in an efficient market, individuals do not make investment decisions in a vacuum. Instead, "Legions of professional securities analysts and investment advisors make their livelihoods by analyzing massive volumes of information about public companies." It is the job of these securities analysts to "ferret out and analyze information." The shareholders assert that these experts cannot do their job unless issuers disclose material information, which according to the shareholders, include the 23 AERs and possible lawsuits.

Shareholders next argue that a reasonable investor would not reject relevant information simply because the information does not rise to the level of statistical significance. A reasonable investor, according to the shareholders, would consider quantitative information as well as "available background scientific and clinical information indicating that a potential problem was biologically plausible or implausible; case reports suggesting the existence of a problem with sufficient detail to be informative; and the opinions of researchers and treating physicians who have studied the drug's effects." Where the drug provides a significant amount of revenue to the company, a reasonable investor would consider any adverse effect, even isolated ones, in the total mix of information. Consequently, in the view of the shareholders, the court should have held that the shareholders stated a claim under Section 10(b) for omission of material facts and should have allowed the case to proceed to discovery.

SIGNIFICANCE

This case could have wide-reaching effects for manufacturers of drugs and medical devices. The use of statistical significance as a proxy for materiality is particularly problematic when the case is in the pleadings stage, as here. The United States warns in its amicus brief that the adoption of the statistically significant test could result in premature dismissals of cases before the trier of fact even has a chance to decide the case. According to the United States, a case should not be dismissed on the grounds of immateriality at the pleadings stage unless reasonable people could not possibly disagree on the lack of materiality. Moreover, statistics experts, in their brief, worry that such a requirement would place an unreasonable burden on plaintiffs to conduct their own scientific study in the absence of an existing study. This is particularly tricky in the case of AERs, which "gradually trickle in over time."

In *TSC Industries,* the Supreme Court held that in determining materiality, courts must consider the "total mix" of available information. Some amici worry that a ruling in favor of Matrixx could eliminate such a standard. If the Supreme Court were to adopt statistical significance as a standard for materiality, interested professors hypothesize that context would become irrelevant and instead materiality would be determined on the "presence or absence of a mathematically validated association between the drug and the adverse events at issue."

The professors' brief asserts that such an approach treats shareholders as "'nitwits unable to appreciate' the importance of any other information that could affect investment decisions."

In contrast, the Advanced Medical Technology Association claims that if the Court were to rule in favor of Matrixx, then companies selling pharmaceuticals, biotechnology, and medical technology would be compelled to report anecdotal data, "leading in some cases to artificially depressed stock prices and increased volatility, as confused investors seek to separate the true nuggets of value amidst a torrent of unreliable information."

This deluge of information could hurt consumers as well. Some patients may stop taking safe and effective medications when they read of these negative reports. Others may ignore such information because they consider it to be an "overwarning."

For example, when Merck and Schering-Plough announced early results of a study of Vytorin that suggested that use of the drug may cause cancer, stock in both companies declined. A few months later, when the study was complete, however, the FDA concluded that use of Vytorin was unlikely to cause cancer. As one physician explained, "Now you've got a fear out there that I don't think is justified that I think patients and physicians will be reticent to use a drug that I think is very useful clinically." *Brief of BayBio.*

Further, if the Court were to rule in favor of the shareholders, to avoid staggering securities liability, companies might prematurely pull drugs from the market, thus harming consumers.

Jayne Zanglein teaches business law at Western Carolina University. She can be reached at jzanglein@email.wcu.edu or 828.227.7191. Matthew Sullivan is a recent business administration and law graduate from Western Carolina University.

PREVIEW of United States Supreme Court Cases, pages 160–163.

ATTORNEYS FOR THE PARTIES

For Petitioner Matrixx Initiatives, Inc. (Jonathan D. Hacker, 202.383.5300)

For Respondent James Siracusano (David C. Frederick, 202.326.7900)

AMICUS BRIEFS

In Support of Petitioner Matrixx Initiatives, Inc.

Advanced Medical Technology Association (Steven A. Engel, 202.261.3300)

BayBio (Deanne E. Maynard, 202.887.1500)

Consumer Healthcare Products Association and the Council for Responsible Nutrition (Robert A. Long Jr., 202.662.6000)

DRI - The Voice of the Defense Bar (James C. Martin, 412.288.3546)

Natural Products Association (Jonathan F. Cohn, 202.736.8000)

Pharmaceutical Research and Manufacturers of America (David W. Ogden, 202.663.6440)

Product Liability Advisory Council, Inc. (Anne E. Cohen, 212.909.6000)

Securities Industry and Financial Markets Association (Lyle Roberts, 703.734.3100)

Washington Legal Foundation (Richard A. Samp, 202.588.0302)

In Support of Respondent James Siracusano

AARP and North American Securities Administrators Association, Inc. (Jay E. Sushelsky, 202.434.2060)

Economists Robert E. Litan and Joseph R. Mason (Merrill G. Davidoff, 215.875.3000)

Professors at Law and Business Schools (J. Robert Brown Jr., 303.871.6254)

Statistics Experts Professors Deidre N. McCloskey and Stephen T. Ziliak (Edward Labaton, 212.907.0700)

United States (Neal Kumar Katyal, Acting Solicitor General, 202.514.2217)