



## SUPREME COURT DECIDES THE SIGNIFICANCE OF ADVERSE EVENT REPORTS IN SECURITIES FRAUD CASES

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On March 22, 2011, the United States Supreme Court in *Matrixx Initiatives, Inc. v. Siracusan*<sup>1</sup> decided that statistical significance is not a threshold pleading requirement in securities fraud claims based solely on the failure to disclose adverse information regarding a product. The Ninth Circuit Court of Appeals had ruled that the Plaintiff was not required to show that the product caused a “statistically significant” number of adverse events to plead the materiality element in securities fraud claims. On appeal to the Supreme Court, Matrixx Initiatives, Inc. argued that statistical significance should be a threshold pleading requirement for a plaintiff to establish before pursuing a securities fraud case based solely on the failure to disclose adverse event reports. Plaintiff, on the other hand, asserted that the statistical significance standard is contrary to the materiality inquiry, which takes into account the total mix of evidence, not just adverse event reports. The Supreme Court agreed with the Plaintiff. Although it acknowledged the relevance and utility of statistical significance during the evidentiary stages of litigation, the Court decided that requiring a showing of statistical significance at the pleading stage

would arbitrarily impose a bright line rule that excludes multiple factors used to assess the safety of a product.

Clearly, the Supreme Court’s decision will have an impact on securities fraud litigation going forward. However, the Court’s ruling may also reverberate beyond the courthouse and have profound effects on the public disclosure practices and FDA reporting policies of companies that manufacture and market products, the information available to investors, and the decisions of the end users of the products.

### The Adverse Event Reports at Issue in *Matrixx Initiatives*

Matrixx, through its wholly-owned subsidiary Zicam LLC, marketed the product Zicam Cold Remedy Nasal Gel (“Zicam”). Plaintiff filed a class action lawsuit alleging that Matrixx violated the Securities Exchange Act by failing to disclose information associating Zicam with a condition called anosmia, which is the loss of the sense of smell.

Specifically, Plaintiff claimed that Matrixx failed to disclose that it was aware of as many as twenty-three cases of people claiming to have developed anosmia

<sup>1</sup> No. 09-1156, slip op. at 6 (U.S. March 22, 2011).

after using Zicam. First, in December 1999, Matrixx was informed of a patient who claimed he developed anosmia after using Zicam. Then, in September 2002, Matrixx received information on a second claim. A year later, Matrixx was informed that several physicians planned to submit findings regarding ten additional cases in a presentation to the American Rhinologic Society. Plaintiff also claimed that Matrixx was aware of four lawsuits, with a total of nine plaintiffs, raising similar allegations. Nevertheless, in press releases, statements made during earnings conferences and its Form 10-Q filings, Matrixx made statements celebrating Zicam's net sales, but did not disclose its knowledge of the adverse event reports or the pending litigation. Additionally, in response to reports regarding an FDA investigation of Zicam in early 2004, Matrixx issued press releases denying the reports linking Zicam to anosmia as false and misleading.

### The Underlying Allegations

Plaintiff alleged that Matrixx violated Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5, which prohibits fraud and deceit in connection with the purchase or sale of any security.<sup>2</sup> To state a claim for securities fraud, the complaint must allege, *inter alia*, a material misrepresentation or omission and scienter.<sup>3</sup> An omitted fact is material 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 available."<sup>4</sup> With respect to scienter, the plaintiff must allege, with particularity, facts giving rise to a strong inference that the defendant had an intention to deceive, manipulate or defraud; and the pleaded facts must render "an inference of scienter *at least as likely as any plausible opposing interest*."<sup>5</sup>

Plaintiff alleged that Matrixx's statements regarding the safety of Zicam and its failure to disclose adverse information regarding Zicam's connection to anosmia materially misled the investing public and inflated the price of Matrixx stock. Plaintiff also asserted that Matrixx acted with scienter because it was aware that

numerous users of Zicam had experienced anosmia at the time the statements were made.

However, the district court disagreed and granted Matrixx's motion to dismiss on the grounds that Plaintiff failed to sufficiently allege materiality and scienter. Importantly, the district court determined that "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."<sup>6</sup> With respect to the Zicam adverse event reports, the district court found that Plaintiff failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publicly disclose the adverse events reports a material omission. In regard to scienter, the district court concluded that there "was no evidence that Matrixx "disbelieved [its] statements as to the safety of Zicam," or attempted to profit from the public statements."<sup>7</sup>

### The Ninth Circuit Rejected the Statistical Significance Standard

The Ninth Circuit Court of Appeals reversed the district court's ruling and concluded that the district court "erred in relying on the statistical significance standard to conclude that [Plaintiff] failed to allege materiality."<sup>8</sup> The Court determined that reliance on the statistical significance standard was inconsistent with the rejection of bright-line rules to determine materiality and the emphasis on having the trier of fact determine materiality based on the total mix of evidence.

### The Statistical Significance Standard

The statistical significance standard was introduced in two Second Circuit appeals from the *In re Carter-Wallace, Inc. Securities Litigation* matter.<sup>9</sup> In the underlying *Carter Wallace* matter, the plaintiffs brought a securities fraud action against Carter-Wallace alleging that it made false and misleading statements through advertisements in medical journals claiming that its anti-epileptic drug, Felbatol, was safe, when, in fact, there were 10 deaths associated with Felbatol. In *Carter-Wallace I*, the statistical significance standard

<sup>2</sup> Securities Exchange Act of 1934, 15 U.S.C. 78j(b) and 17 C.F.R. § 10b-5(b)

<sup>3</sup> *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

<sup>4</sup> *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

<sup>5</sup> *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007) (emphasis in original).

<sup>6</sup> *Siracusano v. Matrixx Initiatives, Inc., et al.* 2005 WL 3970117 (D. Ariz.) at \*5.

<sup>7</sup> *Id.* at \*8.

<sup>8</sup> *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 (9th Cir. 2009).

<sup>9</sup> *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153 (2d Cir. 1998) ("*Carter-Wallace I*") and *In re Carter-Wallace, Inc. Securities Litigation* 220 F.3d 36 (2d Cir. 2000) ("*Carter-Wallace II*").

was applied to the materiality element, whereas the Court in *Carter-Wallace II* applied the standard to the scienter element.

In *Carter-Wallace I*, the Court determined that Carter-Wallace did not have a duty to disclose the deaths related to Felbatol and, therefore, its statements were not materially misleading, until it had information providing “statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—the use of the drugs and are sufficiently serious and frequent to affect future earnings.”<sup>10</sup> In *Carter-Wallace II*, the Court determined that the *Carter Wallace I* ruling that the medical reports did not demonstrate a statistically significant link between Felbatol and any illness was also fatal to the plaintiffs’ claims regarding scienter because without a “statistical link between Felbatol and any adverse side effect . . . the pleadings do not give rise to a strong inference of fraudulent intent.”<sup>11</sup>

The Third Circuit Court of Appeals followed suit in *Oran v. Stafford*,<sup>12</sup> where the plaintiffs claimed that the defendant failed to disclose information pertaining to hundreds of adverse reaction reports linking its drugs to heart valve damage. The Court affirmed the district court’s dismissal of the plaintiffs’ claims, finding that the plaintiffs did not allege that the adverse event reports established any statistical significant relationship between the defendant’s products and heart disease. More recently, the First Circuit Court of Appeals applied the statistical significance standard to the scienter requirement in *New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec, Inc.*,<sup>13</sup> where a drug manufacturer was accused of securities fraud because it failed to disclose information pertaining to eight patients out of 3900 who suffered infections during clinical trials, including two who died. In affirming the dismissal, the First Circuit Court determined that the “incidence rate of 0.2% . . . is no basis to conclude that [the] results . . . were statistically significant.”<sup>14</sup>

### The Ninth Circuit Decision

In *Matrixx*, the Ninth Circuit Court of Appeals found that applying the statistical significance standard

to the materiality analysis erroneously took the decision away from the trier of fact, which was contrary to the Supreme Court’s rejection of the adoption of a bright line rule to determine materiality in *Basic, Inc. v. Levinson*.<sup>15</sup> In *Basic*, the plaintiffs brought a securities fraud claim against Basic, Inc. alleging that material misrepresentations had been made by denials of merger negotiations prior to the official announcement. The defendant requested that the Court use an “agreement in principle” test to determine materiality, pursuant to which merger discussions would not become material until an agreement in principal was made as to the price and structure of the transaction. In rejecting the agreement in principle test, the Court determined that “any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive and underinclusive.”<sup>16</sup>

Relying on *Basic*, the Ninth Circuit Court of Appeals rejected the use of the statistical significance standard to determine materiality. Instead, it reviewed all of the evidence to determine that the reports associating Zicam with anosmia was information that a reasonable investor would have considered significant and, thus, were material. Further, with respect to scienter, the Court determined that at the time of the press releases claiming that the link between Zicam and anosmia was completely unfounded, Matrixx was aware of at least 21 cases of anosmia associated with the use of Zicam, including several lawsuits. Looking at the complaint as a whole, therefore, the Court ruled that the inference that Matrixx withheld information regarding Zicam’s link to anosmia intentionally was at least as compelling as the inference that Matrixx withheld the information innocently.

### The Appeal to the Supreme Court

On appeal to the Supreme Court, Matrixx argued in its brief<sup>17</sup> that the need for statistical significance is due to the fact that adverse event reports are, at best, “anecdotal hearsay” and “not reliable indicators of a causal association between use of the drug and the reported adverse event.” Matrixx asserted that when the statis-

<sup>10</sup> *Carter Wallace I*, 150 F.3d at 157.

<sup>11</sup> *Carter Wallace II*, 220 F.3d at 42.

<sup>12</sup> 226 F.3d 275 (3d Cir. 2000)

<sup>13</sup> 537 F.3d 35 (1st Cir. 2008)

<sup>14</sup> *Id.* at 50.

<sup>15</sup> 485 U.S. 224 (1988)

<sup>16</sup> *Id.* at 236.

<sup>17</sup> Brief for Petitioners, *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156).

tical significance standard is applied to the underlying litigation, Plaintiff cannot allege facts establishing that the rate of anosmia among Zicam users exceeded the rate of anosmia among people who do not use Zicam by a statistically significant degree. Accordingly, the reports of anosmia were not material information that needed to be disclosed, and was not enough to establish an inference that Matrixx intentionally withheld the information.

On the other hand, Plaintiff argued in its brief<sup>18</sup> that Matrixx was attempting “to elevate an arbitrary threshold—statistical significance—into a rule of law.” In fact, Plaintiff argued that Matrixx overstated the prior decisions utilizing the statistical significance standard in that the decisions did not mention, let alone reject, the materiality of non-statistical information about a product’s effect, such as cases studies and physician’s clinical opinions. Additionally, Plaintiff pointed out that the rulings applying the statistical significance standard were rendered at the evidentiary stages of the cases, not the pleading stage. Therefore, requiring a plaintiff to allege a finding of statistical significance at the pleading stage would prematurely lead to a battle of the experts.

The Supreme Court agreed with Plaintiff. Specifically, the Court concluded that the materiality of adverse event reports cannot be reduced to the statistical significant rule because it is a bright line rule that would “artificially exclude information that ‘would otherwise be considered significant to the trading decision of a reasonable investor.’”<sup>19</sup> The Court concluded that adverse events reports come in many forms and assessing their materiality is a fact specific inquiry. “That is not to say that statistical significance (or the lack thereof) is irrelevant - only that it is not dispositive of every case.”<sup>20</sup> Applying the analysis from *Basic*, the Court determined Plaintiff adequately pled materiality because the information available revealed a plausible causal relationship between Zicam and anosmia that a reasonable investor would have changed the “total mix” information. Likewise, the allegations taken together give rise to an inference that Matrixx elected not to disclose the reports of adverse events, not because it believed they were meaningless, but because it understood the likely effect on the market.

### The Possible Effects Of the Supreme Court’s Decision

The Court’s decision clarified the role of statistical significance in securities fraud cases and will have an impact on how litigants prosecute and defend such claims. However, the Court’s decision will also reach beyond the courtroom.

The most notable impact may be on public disclosure policies. In its ruling, the Court determined that concerns regarding companies being required to disclose all reports of adverse events are overstated. First, the Court noted that drug companies and other product manufacturers are already required to report adverse drug experiences, therefore, full disclosure can be achieved with minimal cost increases. Moreover, the rejection of the statistical significance standard does not require disclosure of all adverse reports related to products—companies can remain silent about the safety and profitability of their products and “control what they have to disclose . . . by controlling what they say to the market.”<sup>21</sup>

However proponents of the statistical significance standard maintain that anything less than a bright line rule will put companies in a “damned if they do, and damned if they don’t” scenario; *i.e.*, if a company discloses all adverse reports there could be an unwarranted decline in stock value, but if a company fails to disclose adverse information it might draw unwarranted securities fraud claims. They argue that statistical significance is a deliberative process that provides companies and regulators adequate time to vet scientific data to ensure that the public does not react prematurely to public misperceptions of dangerousness.

In light of the impact on companies’ public disclosure practices, it follows naturally that the Court’s decision could also impact investors. The Court took the position that more information is better, even if some of it proves to be erroneous. A reasonable investor may consider anecdotal information regarding adverse events important, even if they do not prove that the drug causes the effect. As such, full disclosure benefits investors by allowing them to make informed investment decisions and the market will decide whether an adverse event report conveys relevant information. Matrixx and proponents of the

<sup>18</sup> Brief for Respondents, *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156).

<sup>19</sup> *Matrixx Initiatives, Inc., supra*, No. 09-1156, slip op. at 11.

<sup>20</sup> *Id.* at 15.

<sup>21</sup> *Id.* at 16; see also Brief for the United States As Amicus Curiae Supporting Respondents: *Matrixx Initiatives, Inc., v. Siracusano* (No. 09-1156) at p. 27.

statistical significant standard assert that, unless adverse events occur to a statistically significant degree, there is no substantial likelihood that the reasonable investor would rely on adverse event reports as having any bearing on the safety of a drug or device. Therefore, flooding the market with likely meaningless adverse event reports could be detrimental to investors.

Additionally, the end users of the products may be affected by what companies are required and or motivated to disclose to the public. Indeed, the premature disclosure of adverse event reports to the public may discourage participation in clinical trials or cause individuals to discontinue their use of medications or products that are beneficial to them. When doctors and consumers learn of adverse reports, particularly from the company itself, they become reluctant to prescribe and use those drugs, even when there is no evidence from scientific studies to support any association between the drug and the adverse event.<sup>22</sup> The disclosure of statistically insignificant adverse event reports, therefore, may lead to investor confusion and stock fluctuation, which will harm manufacturers, investors, consumers and patients.

Lastly, the Court's decision may even impact the goals of regulatory agencies, like the FDA. Proponents of the statistical significance standard claim that the Ninth Circuit's ruling could encroach upon regulatory agencies' goals in monitoring adverse events associated with drugs and devices.<sup>23</sup> For example, the FDA requires drug and medical device manufacturers to report "serious adverse events" to enable

the FDA to analyze the threat associated with a particular product.<sup>24</sup> The Court's ruling could interfere with that scheme by compelling a company to disclose not only serious adverse event reports, but all adverse event reports about a drug or device, even though the FDA has not deemed them substantial enough to warrant reporting. Consequently, the Court's repudiation of the statistical significance standard may indirectly interfere with the regulatory process of the FDA and other regulatory agencies.

Based on the foregoing, many will be monitoring the aftermath of the Supreme Court's decision with respect to the utility of the statistical significance standard in securities fraud claims. Undoubtedly, the Court's ruling will curb the reliance on the statistical significant standard, but the Court's decision also makes clear that it is not irrelevant to the materiality and scienter analysis in securities fraud claims. More importantly, the Court's decision may reach beyond the pleading, discovery and evidentiary battles waged in securities fraud cases and affect the decisions of manufacturers, investors, and the end users of drugs, medical devices, and a plethora of other consumer products.



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<sup>22</sup> Brief of BayBio as Amici Curiae Supporting Petitioners: *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156) at pp. 23-26.

<sup>23</sup> Brief for the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization as Amici Curiae Supporting Petitioners: *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156) at pp. 12-30.

<sup>24</sup> Brief of the Natural Products Association as Amici Curiae in Support of Petitioners: *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-115) at pp. 15-18.