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High Court Rejects 'Statistical Significance' as Materiality Test for Pharma Securities Fraud

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In a unanimous decision, the Supreme Court has rejected the argument that the risk of side effects from a pharmaceutical product can never be "material" under the securities laws so long as the risk is not known to be statistically significant. Matrixx Initiatives, Inc. v. Siracusano, *No. 09-1156, 563 U.S. ____, 2011 WL 977060, slip op. at 1 (Mar. 22, 2011). In so doing, the Court (in an opinion by Justice Sotomayor) once again rejected a "bright line" test in favor of its traditional approach to materiality, which requires an analysis of the "total mix" of information on the subject available to investors, including the source, context and content of the reports of side effects, and the nature of the company's public statements on the subject.*

The *Matrixx* decision deprives life sciences companies of an argument that, if it had been accepted, would have substituted a bright-line test for the often-murky question of when statistically insignificant but nevertheless worrisome adverse drug reaction reports must be disclosed. That aside, *Matrixx* really does not move the meter on materiality or scienter. The Court's careful opinion reaffirms existing precedent and, in so doing, stresses the sort of allegations that made the complaint in *Matrixx* more than plausible, even in a post-*Twombly* and -*Iqbal* world where a complaint must be plausible to survive a motion to dismiss. The opinion also reminds one that sometimes silence is the best policy: the Court stressed allegations that Matrixx publicly attacked the adverse reports as insignificant despite having no statistically significant data disproving them. As the Court noted, silence absent a duty to speak is not actionable under the securities laws. Issuers should thus think twice before opening their mouths and shy away from the sort of broad categorical statements about their business or products that adverse information — even statistically insignificant adverse information — could render materially misleading.

Background: The flagship product of defendant Matrixx is the Zicam® family of treatments for the common cold. Plaintiffs alleged that Matrixx had received but failed to disclose doctors' reports linking Zicam to a potentially permanent loss of smell ("anosmia") while at the same time publicly forecasting increasing sales and profits from Zicam. Later, when the reports of a possible link between Zicam and

anosmia begun to reach the public, Matrixx dismissed the reports as inaccurate and stated that Zicam's safety was well-established despite having conducted no tests itself, let alone tests disproving the adverse events reports.

The litigation: Plaintiffs alleged that Matrixx had violated §10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5 by misrepresenting the safety of its products and the related strength of its financial outlook. To state a claim that could survive a motion to dismiss, the plaintiffs needed to plead facts that demonstrated misrepresentations or omissions by Matrixx that were "material" to investors, as well as "scienter," a state of mind sometimes described as "reckless disregard" of the truth. Slip op. at 2, 19-20. Matrixx, in moving to dismiss the complaint, argued that its alleged misrepresentations about Zicam could not be material because plaintiffs did not allege a statistically significant number of reports linking Zicam to anosmia. The trial court agreed with Matrixx, but the Court of Appeals reversed, and the Supreme Court affirmed the Court of Appeals' judgment.

The Court's ruling on materiality: The Court declined the bright-line statistical-significance test urged by Matrixx, instead holding that the allegations sufficiently showed a plausible link between Zicam and anosmia that was material under the standard that the Court previously articulated in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988). Under *Basic*, courts use a flexible standard of materiality that requires an analysis of whether 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 231-32 (quoting *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

In declining to adopt the bright-line rule proposed by Matrixx, the Court reasoned that statistical significance is not the only indicator of causation relied upon by reasonable people. It noted that medical experts and researchers and the Food and Drug Administration ("FDA") routinely rely on evidence other than statistically significant data to establish an inference of causation. Slip op. at 12-13. The Court stated that a reasonable investor could likewise act on the same kinds of other evidence. *Id.* at 15. While "something more" than mere existence of adverse event reports is needed to satisfy the materiality standard, that "something more" need not necessarily be reports that establish a statistically significant risk that the product is causing adverse events—materiality can come more generally from the source, content and context of the reports.

"Something more": The Court held that plaintiffs had adequately alleged "something more" in claiming that Matrixx publicly denied any problem with the product and forecast increasing profits even after it had received numerous (though not statistically significant) reports of anosmia. In 1999, a neurologist called Matrixx's customer service line to report a possible link between Zicam and the loss of smell "in a cluster of his patients" and alluded to other problems with zinc (the main ingredient of Zicam). *Id.* at 3. In 2002, Matrixx's vice president for research and development called a doctor at a university medical center after receiving a complaint that a patient at the center had lost her sense of smell after using Zicam; the doctor told the VP about studies linking zinc to the loss of smell and sent him abstracts of the studies. *Id.* at 3. By 2003, another doctor at the university had observed 10 patients suffering from anosmia after Zicam use and planned to present the findings at a meeting of the American Rhinologic Society. When Matrixx learned of the presentation, it demanded that the doctors not use Matrixx's name or the names of any of its products. *Id.* at 3-4. And by February 2004, nine plaintiffs had filed four lawsuits claiming that Zicam had damaged their sense of smell. *Id.* at 4.

Despite these reports of adverse events, Matrixx painted a rosy picture of its financial prospects and affirmatively stated that Zicam was safe. It stated that revenues would likely rise 50% and then 80%. *Id.* at 4-5. It warned in a Form 10-Q that there were potential adverse effects to consumer acceptance and

branding that could arise from product liability claims—whether or not those claims were successful—but failed to disclose that product liability claims had in fact been filed. *Id.* at 5. Matrixx's stock dropped twice on news of the controversy: once when news reports surfaced that the FDA was investigating Zicam's link with anosmia and once when the doctor at the university presented his findings on national television. *Id.* at 5-7. Both times Matrixx publicly dismissed reports linking Zicam and anosmia and stated that Zicam's safety was well-established, and it made these public statements despite having not "conducted any studies of its own to disprove that link." *Id.* at 19.

Juxtaposing the seriousness of the side effect with the relatively trivial benefits of a cold remedy, the Court held that the complaint adequately alleged reports that would have made some consumers decide that the risks of Zicam outweighed its benefits, which in turn would threaten Zicam's commercial viability. A reasonable investor likely would view this information as altering the "total mix" of information available about the value of Matrixx because it demonstrated a commercial risk to Matrixx's leading product. *Id.* at 15. That said, the Court took pains to emphasize that silence might have been an option, noting that "companies often can control what they have to disclose … by controlling what they say to the market." *Id.* at 16. But here Matrixx had not chosen silence; rather, it had made statements regarding Zicam's safety—statements that were directly contradicted by information it had in its possession. *Id.* at 16, 18.

The Court's ruling on scienter: The Court also held that plaintiffs had adequately alleged facts giving rise to a strong inference of scienter. Matrixx argued that the most obvious inference from the alleged facts is that Matrixx did not disclose the reports because they were not statistically significant. *Id.* at 20-21. The Court again declined to adopt such a bright-line rule, and held that the alleged facts supported an inference that Matrixx acted recklessly (or perhaps even intentionally) by failing to disclose the reports and publicly stating that Zicam was safe when in fact it had conducted no studies to support the statement. *Id.* at 21. The Court reasoned that it was likely that Matrixx acted not because it believed the reports were meaningless but because it well understood their likely effect on the market. *Id.* at 22. Thus, the allegations satisfied the Court's test for scienter announced in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323-34 (2007), which the Court reaffirmed.

No change in pleadings standards: While the Court allowed the complaint to survive a motion to dismiss, the *Matrixx* decision nevertheless reflects the application of established standards to the specific allegations before the Court. The opinion cites with approval *Twombly*, *Iqbal*, *Basic* and *Tellabs*, among other leading cases, quarreling with none of them. The complaint passed muster not because of any departure from well-established legal standards but because the adverse event reports belied the defendant's bullish public statements. *Matrixx* leaves no doubt that a complaint alleging less egregious and less specific facts may still properly be dismissed.

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