Ninth Circuit Rules That Imperfect Methodology Used By Pharmaceutical Company Does Not Constitute a Securities Law Violation and Clarifies the Supreme Court's Decision in *Matrixx*

On September 6, 2012, the United States Court of Appeals for the Ninth Circuit issued a decision in *In re Rigel Pharmaceutical Securities Litigation*, case number 10-17619 (read the full decision here), which addressed the question of "whether statements concerning statistical results of a clinical trial may be considered false or misleading under Rule 10b-5 because the statistical methodology that produced those results was not the best or most acceptable methodology." The Court answered in the negative, holding that allegations that a pharmaceutical company used an imperfect methodology to present its clinical trial results were insufficient to plead securities law violations.

Rigel tested an arthritis drug on 189 people in Mexico and the US in 2007. The company issued a press release describing results of the phase 2a clinical trial as "statistically significant," with the drug showing "good tolerability." On a conference call, leaders of the company hailed "impressive and statistically significant improvements over placebo." Side effects were acknowledged in a chart and on the call, but the company stressed that lowering the dose helped minimize those side effects. Thereafter, the company presented more detailed results of the study, both at a scientific meeting and via a medical journal article.

The plaintiff alleged that the defendant, Rigel, made false statements regarding the efficacy of the drug, specifically, that Rigel communicated "false" study results and employed an inaccurate and improper statistical analysis. The Court was not persuaded by the allegations, finding that the plaintiff did not allege that Rigel inaccurately reported the results of its statistical analysis or that the company "had chosen or changed their statistical methodology after seeing the unblinded raw data from the clinical trial." Instead, "Plaintiff challenged Defendants' reported statistical results by alleging that Defendants *should have used* Plaintiff's chosen statistical methodology," which the Court held does not amount to fraud:

> Plaintiff's allegations of 'falsity' essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study, wrote the journal article, and selected the article for publication. The allegations therefore concern *two different judgments* about the appropriate statistical methodology to be used by Defendants. *The allegations are not about false statements* (emphasis added).

Implication of the Supreme Court's Decision in *Matrixx*

The Court also rejected the plaintiff's argument that it adequately pled that Rigel's statements regarding safety-related results of the clinical trial were false and misleading in light of the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011). In *Matrixx*, the Supreme Court held that undisclosed adverse event reports need not rise to the level of statistical significance in order to be a material misrepresentation or omission for securities fraud purposes. Rather, the Supreme Court held that the materiality requirement is satisfied 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 made available." Importantly, however, the Supreme Court noted that this does not mean all adverse event reports must be disclosed. The Supreme Court explained that "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy [the 'total mix'] standard. Something more is needed, but that something is not limited to statistical significance and can come from the 'source, content, and context of the reports.'" The Supreme Court also emphasized that the securities laws "do not create an affirmative duty to disclose any and all material information."

In *Rigel*, the plaintiff argued that under *Matrixx*, since the company disclosed information regarding "key" safety results, it was required to disclose all material information regarding safety. The Ninth Circuit rejected this argument, finding that "*Matrixx* established that section 10(b)(5) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information; section 10(b) and Rule 10b-5 prohibit only misleading and

untrue statements, not statements that are incomplete ... Thus, as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety related results and even if investors would consider the omitted information significant." The Court emphasized that the company: (1) specifically noted that it was disclosing only "key safety results" and not "all safety results"; (2) identified clearly the criteria for inclusion (e.g., for hypertension, it included only moderate or severe side effects); and (3) never claimed that the reported results included every occurrence of every possible side effect. Thus, the Court concluded that the plaintiff had not adequately alleged that the initial statements related to possible side effects were false or misleading.

Key Takeaways

Methodology As a Basis For Liability

- *Rigel* held that allegations that a pharmaceutical company used flawed methodology to present clinical trial results would not suffice for purposes of alleging a misrepresentation under the securities law as long as the company accurately discloses its methodology and reports the results of its statistical analysis.

Process Matters

- The decision, however, indicates that there may be liability where a company chooses to change its statistical methodology after seeing clinical trial data or where a company announces statistical results that are obtained using a methodology different from the methodology used as part of the clinical trial.

Duty to Disclose Generally: Putting the Subject "In Play"

- The decision also clarifies the Supreme Court's decision in *Matrixx* regarding a company's affirmative duty to disclose information.
- While *Matrixx* rejected the bright-line rule of statistical significance for determining when adverse event reports are material for §10(b) purposes, the Supreme Court in *Matrixx* was careful to stop short of requiring pharmaceutical manufacturers to disclose all reports of adverse events.
- *Matrixx* did not create an affirmative duty for a pharmaceutical manufacturer, in the absence of other statements, to disclose potential issues with its products, even if those issues are material. Rather, disclosure is only required when necessary to make other statements the company made, in the light of the circumstances under which they were made, not misleading.
- The Court in *Rigel* clarified that simply putting a subject "in play" is insufficient to create an affirmative duty to disclose all information on that topic as long as the omitted information is not inconsistent with the information that was disclosed on the topic.
- Incomplete statements do not create liability as long as the omissions do not make the actual statements misleading.

Issue to Watch

- The decision creates a strong level of protection for pharmaceutical companies against claims that they did not present results of clinical trials in the fairest possible light. The Ninth Circuit appears to be the first circuit court to weigh in on this issue, so future decisions in this area should be closely watched.

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