Cooley LLP

Case in Point

In re Rigel Pharmaceuticals, Inc. Securities Litigation

On September 6, 2012, Cooley's securities litigators secured a victory for client Rigel Pharmaceuticals, Inc., with significant implications for all companies involved in drug development, when the Ninth Circuit Court of Appeals affirmed the dismissal of a securities fraud suit against Rigel. Importantly, the decision – the first from the Ninth Circuit to address the implication of the landmark Supreme Court decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011) in the drug development and approval process – validates the process followed by many drug development companies of initially releasing "top-line data" from drug trials and later disclosing more detailed data at scientific conferences.

In questions of first impression for the court, the opinion – *In re Rigel Pharmaceuticals, Inc. Securities Litigation*, No. 10-17619 (9th Cir. Sep. 6, 2012) – made two important holdings that impact life science companies. First, the court held that a securities fraud class action should not be allowed to proceed past a motion to dismiss based on allegations that the company should have used a different or allegedly better statistical methodology to evaluate the efficacy of the trial. Second, the court held that the oft-used practice of initially disclosing only top-line data does not render such disclosures false so long as the more detailed data omitted from the disclosures do not render such disclosures misleading.

Background

Rigel is a clinical-stage drug development company that discovers and develops novel, small-molecule drugs for the treatment of inflammatory and autoimmune diseases, certain cancers, and other diseases. One of those drugs is R788, which is being tested for the treatment of rheumatoid arthritis.

The company issued a press release in December 2007 reporting the safety and efficacy results of a Phase IIa clinical study of its drug designed to treat rheumatoid arthritis. The press release reported top-line results which showed a statistically significant improvement for patients in the treatment groups over those in placebo groups. The press release also reported key safety results and side effects, indicating "good tolerability" of the drug by patients.

RESULTS

- The decision provides guidance to all drug development companies releasing clinical trial results.
- The Ninth Circuit rejected the plaintiff's contention that the company should have used a different or allegedly better methodology in interpreting the data.
- The decision also provides protection against after-the-fact challenges to the design of clinical studies and the statistical methodologies used to evaluate the results of such studies.
- The Ninth Circuit held that disclosing only top-line data does not render a disclosure false so long as the more detailed data omitted from the disclosure does not render the disclosure misleading.

Eleven months later, company executives presented more detailed findings from this study at the ACR Annual Scientific Meeting and in an article published in the medical journal *Arthritis and Rheumatism*. The additional details, which had not been part of the 2007 press release, included efficacy data broken down based on geographical locations where the patients were enrolled. The additional data showed a potential country interaction in which, even though similar improvements between drug and placebo groups were observed among patients enrolled in Mexico and the U.S., the Mexican patients had a higher placebo response than U.S. patients. The additional information also included detailed safety results, including information regarding all adverse events suffered by three percent or more of the patient population. Shortly after the ACR meeting, the company's stock price decreased significantly.

The plaintiff asserted securities fraud claims under section 10(b) of the Securities Exchange Act of 1934 and section 11 of the Securities Act of 1933, alleging that the 2007 press release was false and misleading because the statement that the study had shown statistically significant results was based on a flawed statistical methodology and because it failed to report the more detailed safety and efficacy data.

Ninth Circuit Decision

The Ninth Circuit rejected the plaintiff's contention that the December 2007 disclosures were fraudulent because the company used an allegedly "flawed methodology" in interpreting the data. In rejecting plaintiff's argument, the court explained that plaintiff's allegations of falsity failed because they amounted to nothing more than disagreements about the design of the study and appropriate statistical methodology to be used in evaluating the results of the study.

The court also addressed, for the first time, the impact of the *Matrixx* decision in the context of the disclosure of results of drug clinical trials by life sciences companies. In *Matrixx*, the Supreme Court rejected a Ninth Circuit decision holding that serious adverse events experienced after the commercial launch of a drug need only be disclosed if they rise to the level of statistical significance. The plaintiff in *Rigel* argued that, under *Matrixx*, once a company chooses to disclose any safety information related to a clinical trial, it must disclose all material safety information. The Ninth Circuit squarely rejected this contention. The court concluded, "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."

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