September 11, 2012

On September 6, 2012, Cooley LLP securities litigators secured a victory for client Rigel Pharmaceuticals, Inc. ("Rigel"), 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 the company. Importantly, the decision—the first from the Ninth Circuit to address the implication of last year's landmark Supreme Court decision in *Matrixx Initiatives, Inc. v. Siracusano,* 131 S.Ct. 1309 (2011) (*"Matrixx"*) 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 sciences 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.

In *Rigel,* 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. 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 rate 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, in late 2008, the company's stock price decreased significantly.

The plaintiff asserted securities fraud claims under section 10(b) of the Securities Exchange Act of 1934, 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 that investors would find important. The Ninth Circuit rejected both arguments.

First, the Court rejected the plaintiff's contention that the December 2007 disclosures were fraudulent because the company used an allegedly "flawed methodology" in interpreting the data. Among other things, the plaintiff argued that a different statistical methodology should have been used to determine the efficacy of the trial (that is, to calculate the "p-value") in light of the potential country interaction reflected in the detailed data. The Court noted that "[n]either the Supreme Court nor this court has addressed" such a challenge. 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:

Plaintiff … did not allege that Defendants 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…. Thus, 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.

The Court concluded that "[b]ecause Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results."

Second, the Court 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 *Matrixx* court made it clear that not all material adverse events would be material and, more importantly, that not all material adverse events would have to be disclosed." 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."

The Court also affirmed the dismissal of the plaintiff's claims under section 11 of the Securities Act of 1933. Plaintiff had alleged that similar representations regarding the clinical study results made by Rigel in its secondary offering were misleading and, thus, actionable. The Court held that the plaintiff was obligated to meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) because the section 11 claims relied on the same misrepresentations as the fraud claims. The Court concluded that the plaintiff failed to meet these pleading requirements.

The Court's holding in *Rigel* should provide some guidance and peace of mind to all drug development companies releasing clinical trial results. As always, companies should adhere to a pre-determined methodology in conducting and analyzing their clinical trials and accurately report the results of that analysis. When disclosing the "top-line" results from such studies, the Ninth Circuit's decision in *Rigel* should provide significant protection from securities fraud claims so long as those results, though incomplete, are not misleading. The decision will also provide 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 Cooley team was led by John C. Dwyer, co-chair of Cooley's Securities Litigation Group, and included partner Shannon Eagan and associates Jeff Kaban and Bennett Miller.

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