

Lessons From In Re Rigel Pharmaceuticals

Law360, New York (September 19, 2012, 10:56 AM ET) -- In *In re Rigel Pharmaceuticals Inc. Securities Litigation* (9th Cir. Sept. 6, 2012), the United States Court of Appeals for the Ninth Circuit affirmed the dismissal of a putative securities class action against Rigel Pharmaceuticals Inc., certain of Rigel's directors and officers, and underwriters of Rigel's February 2008 stock offering.

In a published opinion, the court held plaintiffs failed to sufficiently plead a false or misleading statement, and that the complaint's allegations failed to meet the heightened requirements for pleading scienter under the Private Securities Litigation Reform Act of 1995. In so holding, the Ninth Circuit held that mere disagreement with statistical methodology employed in a clinical drug trial is not sufficient to state a securities fraud claim.

Rigel is a clinical-stage drug development company that discovers and develops small-molecule drugs for the treatment of inflammatory and autoimmune diseases, certain cancers and other diseases. One of those drugs, R788, is aimed at treating and stopping the progression of rheumatoid arthritis.

To evaluate the preliminary efficacy and safety of R788, Rigel conducted a multicenter, randomized, double-blind Phase IIa clinical trial using the American College of Rheumatology (ACR) criteria. The results of this clinical trial were initially released by Rigel in a December 2007 press release and conference call, and more extensively in later scientific conferences and journal articles. Rigel also announced its goal to obtain a partner for the future development of R788.

In 2009, a purchaser of Rigel stock brought a putative class action in the United States District Court for the Northern District of California charging securities fraud in violation of Sections 10(b) of the Securities Exchange Act. Plaintiffs also brought claims pursuant to Sections 11 and 12 of the Securities Act, based on the registration statement and prospectus issued in connection with Rigel's February 2008 stock offering.

Plaintiffs alleged that, by knowingly making false or misleading statements regarding the results of the clinical drug trial and about partnership prospects for Rigel, Rigel executives caused the putative class members to purchase Rigel stock at artificially inflated prices. The district court dismissed the action, holding that the complaint failed to sufficiently allege a false or misleading statement regarding efficacy of the drug because, among other reasons, disagreements over statistical methodology and study design are insufficient to allege a materially false statement, and failed to sufficiently allege scienter.

The Ninth Circuit affirmed. In a published opinion, the court held that to allege falsity, plaintiffs must allege something more than a mere disagreement with the statistical methodology of the clinical drug trial. That plaintiffs disagreed with the researchers about the import of the data and the study's design did not make the results of the clinical trial false or misleading.

Plaintiffs instead must set forth specific facts either that the results of the statistical analysis were inaccurately reported or false, or that defendants had chosen or changed the statistical methodology after seeing the unblinded raw data from the clinical trial, or that defendants otherwise misrepresented or manipulated the results of the clinical trial. The court concluded that alleging that defendants "should have used different statistical methodology in their drug trials is not sufficient to allege falsity."

The court found that plaintiffs' other attempts to plead false or misleading statements likewise failed. Plaintiffs alleged that the December 2007 press release was misleading because it provided incomplete disclosures as to the clinical trial's results on country interaction and R788 dose response, and the drug's potential side-effects.

The court disagreed that omission of some information from the press release, which was later disclosed in medical journals, made the initial statements misleading. The court explained that the press release clearly identified its table of results as "key safety results" and did not purport to be an exhaustive list. Moreover, the initial disclosures were consistent with the later — and more extensive — disclosures in the medical journal articles.

That some investors might have wanted more information than that provided in the press release does not make the preliminary disclosures false or misleading. Plaintiffs also alleged that Rigel's optimistic statements about its partnership prospects were false or misleading. Finding that plaintiffs did not allege that defendants knew or expected that these predictions were inaccurate at the time they were made, the court concluded plaintiffs' allegations were insufficient to plead falsity. Defendants were not liable for expectations or projections unless they knew the facts did not support the opinion stated.

The Ninth Circuit also concluded that the district court did not err when it determined that plaintiffs failed to meet the requirements for pleading scienter under the Reform Act. Plaintiffs had attempted to plead scienter by alleging that defendants knew of the detailed clinical trial results when they made the allegedly fraudulent statements and by alleging that defendants had financial motives for making fraudulent statements.

First, the court rejected that scienter could be established through defendants' mere knowledge of the trial results without corresponding allegations that defendants also believed their statements were false or misleading. Second, the court also rejected plaintiffs' attempts to plead scienter through motive allegations.

The court explained that allegations of routine corporate objectives, such as the desire to obtain good financing and expand, are not, without more, sufficient to allege scienter. The court noted that none of the defendants sold stock during the period when they would have benefited from the allegedly fraudulent statements, thereby diminishing any inference of scienter, and explained that the defendants likely would not have voluntarily disclosed all of the data and statistical methodology, especially to knowledgeable doctors and scientists, if they had intended to defraud.

The court affirmed dismissal of the complaint's Section 11 cause of action, as it was based on the section 10(b) allegations of fraud, and Section 15 and 20(a) claims, as they required underlying primary violations of the securities laws.

There are four main takeaways from Rigel. First, it clearly establishes that mere disagreement over scientific methods is insufficient to plead falsity for a securities fraud claim. Second, it reaffirms that a statement is not false simply because it is an incomplete statement; it must be misleadingly incomplete. Third, it implicitly applied the rule that statements of opinion or belief are actionable only where the speaker does not believe the stated opinion or belief. Fourth, it reaffirms three important components of a scienter analysis: generic corporate motives, without more, are insufficient to plead scienter; the absence of insider stock sales undermines scienter; and actions inconsistent with scienter suggest its absence.

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