Securities Regulation Daily Wrap Up, FRAUD AND MANIPULATION—E.D. Mo.: Complaint over pricey pregnancy drug failed to state claim, (Mar. 28, 2014)

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By Anne Sherry, J.D.

An amended class-action complaint alleging false and misleading statements and omissions concerning the prescription drug Makena was dismissed without prejudice to permit one amendment on a limited issue. The complaint, which alleged that K-V Pharmaceutical Co. (K-V) and three of its officers should have known that Makena could not be commercially viable due to its high list price and inadequate financial assistance program, took issue with protected forward-looking statements and otherwise failed to meet PSLRA pleading standards, the court concluded (*In re K-V Pharmaceutical Company Securities Litigation*, March 27, 2014, Fleissig, A.).

Background. In 2008, K-V acquired the rights to a drug to reduce the risk of pre-term birth for at-risk women, which it rebranded Makena, and in 2011 the FDA granted the company exclusive sales rights under the Orphan Drug Act. K-V announced, first in an investor conference call and then in a press release, that Makena would be priced at $1,500 per injection, with patients expected to receive 15 to 20 injections. Following the announcement, March of Dimes withdrew its support for the drug, and two U.S. senators expressed concerns over the list price and the insufficiency of the proposed financial assistance program. On March 30, 2011, the FDA announced that it did not intend to take enforcement action against pharmacies that compounded the equivalent of Makena. Despite K-V's announcement the following day that it was reducing the price of Makena to $690 per injection, its stock price continued to fall.

Alleged misstatements. The plaintiffs claim that K-V knew, or should have known, that Makena would not be commercially successful at a price of $1,500 per injection and without an effective financial assistance program, in large part because the FDA would not enforce K-V's exclusive rights to manufacture and distribute the drug. The plaintiffs claim that the omission of this risk rendered many of K-V's statements in a February 14, 2011, investor conference call materially false and/or misleading.

Forward-looking statements. The court determined that the majority of the challenged statements were forward-looking and were accompanied by meaningful cautionary language. In particular, the company's Form 10-K included as risk factors "the possibility that any product launch may be unsuccessful, including with respect to [Makena], the acceptance of and demand for the company's new pharmaceutical products, including [Makena], and the possibility that any period of exclusivity may not be realized, including with respect to [Makena]." Therefore, other than K-V's statements in the investor call about the financial assistance program, the statements were protected by the PSLRA safe harbor.

Statements about financial assistance. With respect to the statements about the financial assistance program, the court concluded that the complaint did not meet the PSLRA's pleading standards. The plaintiffs did not state what financial assistance K-V offered and how it would fail to expand access for lower-income patients. The complaint also failed to set forth any factual basis for the defendants' knowledge that the financial plan was inadequate. However, the court allowed leave to amend the complaint with respect to these statements because if they were indeed false, there could be an argument that the other elements of a Sec. 10(b) fraud claim could be adequately pleaded with respect to Makena's commercial viability.

The case is No. 4:11CV01816 AGF.

Attorneys: Naumon A. Amjed (Kessler and Topaz) for Frank Julianello. Eric C. Schmale (Gibson & Dunn) for K-V Pharmaceutical Co.

Companies: K-V Pharmaceutical Co.

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