Securities Regulation Daily Wrap Up, FRAUD AND MANIPULATION—S.D.N.Y.: Allegations that EpiPen maker misled investors largely survive, (Mar. 29, 2018)

Securities Regulation Daily Wrap Up

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By Rebecca Kahn, J.D.

Claims that a drug company violated U.S. and Israeli securities laws by misclassifying its EpiPen, colluding to inflate drug prices, and making materially misleading statements largely survived a motion to dismiss. The drug company was repeatedly warned by government authorities that it had misclassified the EpiPen for purposes of Medicaid plan rebates. Therefore, warning statements that government action might occur in the future had been misleading. The court dismissed Sherman Act claims as conclusory and declined to exercise supplemental jurisdiction over Israeli law claims (*In re Mylan, N.V. Securities Litigation*, March 28, 2018, Oetken, J.P.).

Class action. A securities class action brought against drug company Mylan N.V. and its officers alleged that Mylan knowingly misclassified its EpiPen Auto-Injector ("EpiPen") for purposes of Medicaid rebates; entered into anticompetitive agreements to inflate drug prices; and made materially misleading statements to investors, violating U.S. and Israeli securities laws. Investors brought this action on behalf of individuals who purchased Mylan common stock between February 2012 and January 2017 on the NASDAQ or the Tel Aviv Stock Exchange. It named defendants as Mylan N.V., related companies and certain of its executives and officers (collectively, "Mylan"). The complaint alleged that Mylan engaged in Medicaid misclassification and antitrust violations. Mylan moved to dismiss all claims for failure to state a claim upon which relief can be granted and to dismiss Israeli law claims for lack of jurisdiction.

Settlement. The Complaint alleged that Mylan unlawfully misclassified the EpiPen as a generic drug for purposes of a program requiring pharmaceutical companies to give rebates to the Centers for Medicare & Medicaid Services ("CMS"). Mylan's decision to classify the EpiPen as it did allegedly "saved the company over $700 million." The CMS had informed Mylan on "multiple occasions" that it had misclassified the EpiPen and ultimately, Mylan was subpoenaed by the DOJ. In October of 2016, it agreed to a $465 million settlement. Although it agreed to reclassify the EpiPen, Mylan did not admit to any wrongdoing. Despite numerous federal and state investigations into anticompetitive misconduct, Mylan has never been found liable for such misconduct.

Material misrepresentations. The Complaint alleged that Mylan's statements of income and the market, statements of Medicaid rebate rates and their complexity and regulatory risk were half-truths, requiring additional disclosures. Unlike Mylan's 10-K and 10-Q statements of income, which were found inactionable, Mylan's statements in its Forms 8-K squarely put its sources of income at issue. For example, the court noted that attributing EpiPen's strength to "favorable pricing and volume" may have been misleading without any additional statement disclosing that the EpiPen's strength was also due to anticompetitive agreements and knowingly miscalculated Medicaid rebates. Moreover, stating that the generics segment faced "unfavorable pricing" may have been misleading in the absence of a disclosure that low prices were mitigated by price-fixing agreements. While Mylan's statements disclosing some sources of past income created a duty to tell the whole truth about past sources of income, statements explaining past income did not obligate Mylan to disclose future risk.

"Explaining the Market" statements. In Annual Reports issued during the class period, Mylan described the competitive nature of the market in which it sold the EpiPen and generic drugs. The Complaint alleged that these statements failed to disclose the alleged anticompetitive agreements, collusion to fix prices and manipulate the market. The court noted that the Annual Reports were "replete" with statements that characterized the EpiPen and generic drug markets as "very competitive" and "highly sensitive to price." If, as alleged, Mylan had been

engaged in anticompetitive practices in collusion with its competitors, then these statements were misleading in the absence of a disclosure of that anticompetitive conduct.

"Rebate Rate" statements and warnings. Annual Report statements regarding rebate rates also contained possible misleading statements, the court held. In numerous Annual and Quarterly Reports, Mylan warned that its calculations of Medicaid rebate rates and risks could be incorrect. The court found that these statements were inactionable statements of opinion and Plaintiffs failed to adequately and separately allege that Mylan knowingly misclassified the EpiPen and believed the classification scheme to be simple, unambiguous, or objective. However, Mylan's cautionary statements disclosing the future risk of a present fact were potentially misleading because a reasonable investor could have concluded that the warned-of unfavorable events (such as a possible investigation) had not yet occurred. The court noted: "To warn that the untoward may occur when the event is contingent is prudent;" but "to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit." The only reasonable inference an investor could have drawn is that, at the time of the disclosure, Mylan did not affirmatively know that the EpiPen was misclassified. If Mylan knew for certain that the EpiPen was misclassified, then warning about the "risk of errors" could have misled a reasonable investor as to Mylan's then-existing knowledge. Thus, these allegations survived only to the extent that Mylan misrepresented its knowledge about the EpiPen's misclassification.

Scienter and underlying misconduct. The court found that Mylan's Rebate Statements and Regulatory Risk Statements were potentially material even in the absence of illegal conduct because they gave the investor the false impression that its rebate rate had not yet been contradicted by CMS and was not yet subject to a DOJ investigation. A reasonable investor certainly could have found information about that liability "important in deciding how to act," and disclosure of the EpiPen's real rebate rate and the existence of significant governmental scrutiny could have "significantly altered the 'total mix' of information made available" to a reasonable investor. With respect to regulatory scrutiny, the Complaint alleged that "CMS repeatedly informed Mylan that Mylan was misclassifying the EpiPen" and that Defendants were notified of the DOJ investigation by a subpoena in November 2014. Consequently, Plaintiffs plausibly alleged with particularity that Mylan was at least reckless with respect to their Rebate and Regulatory Risk Statements because "the danger was either known to the defendants or so obvious that the defendants must have been aware of it."

Knowingly misclassified. The court was convinced by circumstantial evidence that Mylan knowingly misclassified the EpiPen. A strong inference of scienter was persuasive because of the repeated notifications by CMS that the EpiPen was misclassified. Other circumstantial evidence included the individual Defendants' high-level positions and their signed SOX certifications, the importance of the EpiPen to Mylan's business and Mylan's receipt of the DOJ subpoena. At this stage of the litigation, the Complaint plausibly pleaded that underlying misconduct occurred and that "the inference of scienter is as compelling as the opposing inference of the non-fraudulent intent of the Individual Defendants." Whether the EpiPen was in fact misclassified, and whether the individual Defendants had knowledge of such misclassification, was appropriately the subject of discovery.

Antitrust statements. Mylan allegedly entered into two anticompetitive agreements with respect to the EpiPen. But the court found that the Complaint failed to plausibly allege that either agreement violated the antitrust laws. It offered only conclusory allegations of an illegal pay-for-delay agreement and that Mylan was "able to increase the price of the EpiPen by more than 400% between 2009 and 2016." In addition, the Complaint failed to allege that Mylan's exclusive-dealing agreements with schools had "an actual adverse effect on competition as a whole in the relevant market" or that the arrangements' anticompetitive effects outweighed their procompetitive effects. The Complaint alleged that Mylan's statements were misleading because they failed to disclose that illegal means had inflated Mylan's margins and altered the market. But nowhere did it explain why Mylan's statements would be materially misleading if the agreements were, as a legal matter, not unlawfully anticompetitive. Finally, the Complaint's "sparse allegations of illegality" failed to allege scienter with particularity that Defendants acted with the requisite scienter.

Israeli securities law claim. The Court dismissed the Israeli law claim, declining to exercise supplemental jurisdiction. It found a complex issue of foreign law: whether Israeli courts would apply U.S. securities law or Israeli securities law to a "dual listed" company such as Mylan. The court left this to Israeli court to decide in the first instance.

The case is No. 16-CV-7926 (JPO).

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Companies: Mylan N.V.; Mylan Inc.

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