SEC–Mylan Settlement is an Important Reminder of Investigation Disclosure Considerations

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Capital Markets and Securities

A pharmaceutical company, Mylan, N.V., recently paid $30 million to settle an SEC enforcement action alleging multiple disclosure failures arising from an investigation by the Department of Justice.[1] The SEC charged Mylan with securities fraud and other violations based on its failure to disclose a loss contingency from the investigation and based on allegedly misleading risk factor disclosures. The case serves as an important reminder to public companies to carefully and regularly consider whether and when to disclose pending government investigations, and in particular how such investigations should be addressed in loss contingency and risk factor disclosures.

The DOJ Investigation

The DOJ investigation, launched in November 2014, focused on Mylan's classification of EpiPen, its epinephrine auto-injector, as a generic, instead of branded, drug under the Medicaid Drug Rebate Program, which substantially reduced the amount of rebates Mylan was required to pay to the government. Beginning in 2013, the Centers for Medicare and Medicaid Services ("CMS") had begun questioning Mylan's classification of the EpiPen, and in October 2014 CMS told Mylan that its classification was incorrect.

The DOJ investigation spanned nearly two years before news outlets reported the potential misclassification of EpiPen in September 2016. EpiPen was Mylan's most important drug product during this period, bringing in the highest sales and profits. During that time, Mylan filed multiple periodic reports with the SEC and engaged in private and public offerings of securities, none of which disclosed the existence of the investigation. Mylan publicly disclosed the investigation and the associated liability in early October 2016, shortly after reaching a settlement in principle with DOJ that called for the company to pay $465 million.

Loss Contingencies

The SEC alleged in its complaint that Mylan's periodic reports from at least the third quarter of 2015 through the second quarter of 2016 were materially misleading because they did not disclose or accrue for liability relating to the DOJ's investigation. Under Accounting Standard

[1] https://www.sec.gov/news/press-release/2019-194; https://www.sec.gov/litigation/complaints/2019/comp-pr2019-194.pdf

Codification (ASC) 450, a material loss contingency, include pending and threatened litigation and governmental proceedings, must be disclosed if a loss is “reasonably possible” (that is, more than “remote,” although less than “probable”). In addition, if the loss is “probable” and “reasonably estimable,” ASC 450 requires that the company also accrue a charge against income.

The SEC found that Mylan was required to disclose the DOJ investigation as a loss contingency by its third quarter 2015 Form 10-Q because by that time it “knew or should have known that the likelihood of a material loss . . . was reasonably possible.” The SEC based this conclusion on its allegation that, during the course of the investigation, Mylan had provided DOJ with estimates of a range of potential damages for one quarter in 2015 and for the full year 2015. Because DOJ was investigating a potential False Claims Act violation, trebled damages were possible if Mylan knowingly submitted a false claim to the government. In addition, according to the SEC, by its second quarter 2016 Form 10-Q, Mylan should have known that a loss was “probable” and “had sufficient information in its possession to estimate a range of losses.” The SEC took the position that, even if Mylan did not have a best estimate within that range, under ASC 450 it should have accrued the low end of the estimated range as a charge against income.

If a public company is the subject of an investigation, its executives may push to wait to disclose the investigation until a resolution is reached, to avoid reputational or stock price hits or to avoid compromising settlement discussions. However, the Mylan action is a good reminder that ASC 450 prescribes certain disclosures as the possibility of the loss becomes more likely. As an investigation evolves, a public company should regularly evaluate the facts and consider whether it is required to disclose a loss contingency because material loss has become “reasonably possible.” Moreover, once a material loss is “probable,” the company should consider whether it can determine a range of potential losses and accrue a charge against income. These estimates may have already been calculated as part of preparing for settlement discussions. Coordination between the company and its advisors is essential in order to ensure the drafters of the periodic reports have sufficient information about the status of the investigation.

Risk Factors

In the Mylan action, the SEC also alleged that the company’s risk disclosures were misleading because they described risks as merely potential when they had already come to fruition. For example, according to the SEC, after CMS had informed Mylan that EpiPen was misclassified, “Mylan misleadingly stated that the company faced merely *the risk* that CMS may take the position that Mylan’s submissions to CMS were incorrect.” In addition, the SEC alleged that Mylan’s risk factors said that “a governmental authority *may* take a position contrary to a position we have taken” with respect to payments to Medicaid, and that “[w]e cannot assure you that our submissions will not be found by CMS . . . to be . . . incorrect.”

The Mylan settlement drives home the point that public companies should frequently re-assess their risk factor disclosures, rather than just treating them as boilerplate, and in particular should consider whether any of the risks could be viewed as materially misleading because they present as a hypothetical an actual situation that the company is facing. The SEC’s action against Mylan follows a number of other recent enforcement actions focusing on misleading risk factors. Earlier this year, the SEC charged Facebook Inc. with misleading risk factor disclosure because they had “presented the risk of misuse of user data as merely hypothetical when

Facebook knew that a third-party developer had actually misused Facebook user data."[2] And last year, Altaba Inc. (formerly Yahoo! Inc.) settled with the SEC on charges that it had misled investors by failing to disclose that it had suffered "one of the world's largest data breaches."[3] The SEC alleged that, even after the massive breach occurred, Yahoo! had stated in a risk factor that it faced only the risk of data breaches.

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[2] https://www.sec.gov/news/press-release/2019-140
[3] https://www.sec.gov/news/press-release/2018-71