UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF COLUMBIA

SECURITIES AND EXCHANGE COMMISSION 100 F Street, N.E. Washington, D.C. 20549, Plaintiff, v. MYLAN N.V., 1000 Mylan Boulevard Canonsburg, PA 15317 Defendant.	Case No. 1:19-CV-2904 COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission") alleges as follows:

SUMMARY

1. Mylan N.V. ("Mylan") failed to timely disclose to investors a possible loss relating to a nearly two-year Department of Justice ("DOJ") probe into whether Mylan overcharged Medicaid by hundreds of millions of dollars for sales of EpiPen Auto-Injector ("EpiPen") by misclassifying EpiPen as a "generic" or "non-innovator" drug. EpiPen is used to treat severe allergic reactions and was Mylan's largest revenue and profit generating product during the relevant period.

2. When Medicaid patients purchased EpiPen, Mylan was paid from taxpayer-funded Medicaid. Mylan was required to rebate a portion of these revenues to the government. By classifying EpiPen as a generic drug under the Medicaid Drug Rebate Program ("MDRP"), Mylan paid much lower rebates to the government than if it had classified EpiPen as a "branded" or "innovator" drug. In addition, Mylan raised the price of EpiPen more than 500%, but, as a result of

the classification of EpiPen as a generic drug, Mylan avoided paying an additional rebate to the government under the MDRP.

3. In November 2014, Mylan received a subpoena from DOJ as part of its civil investigation into whether Mylan misclassified EpiPen products. As the investigation progressed, Mylan responded to multiple subpoenas and investigative demands, signed tolling agreements, provided damages estimates to DOJ, was informed by DOJ that it was prepared to file suit, and made offers of settlement to DOJ.

4. A public company facing a material loss contingency, such as one arising from a lawsuit or government investigation, is required under accounting principles and the securities laws to (1) disclose the loss contingency if a loss is at least reasonably possible, and (2) record an accrual for the estimated loss if a loss is probable and reasonably estimable. Contrary to these requirements, Mylan failed in its quarterly, annual and other reports, to disclose the loss contingency or accrue for the loss until October 2016, when Mylan announced a $465 million settlement in principle with DOJ. As a result, Mylan's required public filings were false and misleading.

5. Mylan also made misleading statements in its 2014 and 2015 annual reports when it disclosed the risk that the Centers for Medicare and Medicaid Services ("CMS") "***may***" take the position that its submissions to Medicaid were incorrect. In fact, in an October 2014 call, CMS told Mylan that it was misclassifying EpiPen as a generic drug. Instead of disclosing that CMS disagreed with Mylan's classification of EpiPen, Mylan misleadingly presented a potential risk that CMS could disagree.

6. On September 2, 2016, Mylan's stock price dropped significantly (4.7%) after news outlets widely reported that members of Congress accused Mylan of misclassifying EpiPen and underpaying the government.

7. By engaging in the conduct described herein, Mylan violated Sections 17(a)(2) and 17(a)(3) of the Securities Act of 1933 (the "Securities Act") [15 U.S.C. §§ 77q(a)(2) and 77q(a)(3)]; Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Securities Exchange Act of 1934 (the "Exchange Act") [15 U.S.C. §§ 78m(a), 78m(b)(2)(A), and 78m(b)(2)(B)]; and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-1, 240.13a-11, and 240.13a-13].

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to Sections 20 and 22 of the Securities Act [15 U.S.C. §§ 77t and 77v] and Sections 21 and 27 of the Exchange Act [15 U.S.C. §§ 78u and 78aa].

9. Venue is proper in this judicial district pursuant to Section 22 of the Securities Act [15 U.S.C. § 77v] and Section 27 of the Exchange Act [15 U.S.C. § 78aa] because the Defendant transacts business in this district and violations of the securities laws alleged in this Complaint occurred within this district, including the filing of false and misleading reports with the Commission.

10. Mylan, directly or indirectly, made use of the means or instruments of transportation or communication in interstate commerce, or of the mails, or of the facilities of a national securities exchange in connection with the transactions, acts, practices, and courses of business described in this Complaint.

DEFENDANT

11. **Mylan N.V.** is a global pharmaceutical company, incorporated in the Netherlands, with its global center in Canonsburg, Pennsylvania. In February 2015 Mylan N.V. replaced Mylan Inc. as the public reporting company and Mylan Inc. became a wholly owned subsidiary

of Mylan N.V. Mylan's securities are registered pursuant to Section 12(b) of the Exchange Act and trade on the NASDAQ Stock Market. Mylan issued notes in private offerings in December 2015 and June 2016. In June 2016, Mylan offered stock pursuant to a registration statement on Form S-4 in connection with its subsequent acquisition of another company. These securities offerings incorporated one or more of Mylan's false and misleading annual, quarterly and other reports.

FACTS

Mylan Benefits By Classifying EpiPen as a Generic Drug

12. From 2014 through 2016, EpiPen was Mylan's most important and largest drug by sales and profits, generating annual sales of approximately $1 billion. In light of EpiPen's impact on Mylan's overall financial performance, several securities analysts following Mylan created projections related solely to EpiPen's financial performance.

13. From 2014 to 2016, Mylan sold approximately 20% of its annual EpiPen sales to Medicaid patients. Drug pricing for Medicaid patients is determined through statutes, rules and regulations promulgated by Congress and CMS. Among other requirements, pharmaceutical manufacturers must participate in the MDRP in order for their drugs to be covered by Medicaid. Participants in the program must classify each drug sold through Medicaid as "non-innovator multiple source" drugs (referred to herein as "generic" drugs) or "single source" or "innovator multiple source" drugs (referred to herein as "branded" drugs).

14. Pharmaceutical companies generally must pay quarterly rebates to the government for any drugs sold through Medicaid. Rebate rates paid by pharmaceutical companies to the government for generic drugs were much lower than rebate rates for branded drugs.

15. Typically, during the relevant period, drugs approved by the Food and Drug Administration ("FDA") under a new drug application were required to be classified as branded drugs. EpiPen was approved by the FDA pursuant to a new drug application and had other characteristics of a branded drug, such as the lack of any therapeutically equivalent drugs, patent protection, Mylan's significant advertising of EpiPen directed to end-users, and the high price Mylan charged for EpiPen. Nevertheless, Mylan had classified EpiPen as a generic drug under the MDRP from the time it acquired the marketing rights to EpiPen from another pharmaceutical company in 2007. That company, and subsequently Mylan, relied on a 1997 letter expressing the view of a then-CMS employee that it was appropriate to classify EpiPen as a generic drug under the MDRP (the "1997 Letter").

16. Mylan benefitted significantly by classifying EpiPen as a generic drug. Not only did Mylan pay 10% less in baseline rebates, it also did not pay any additional rebate that would have resulted from its increasing the price of EpiPen at a rate greater than the inflation rate. Mylan increased the price of the drug from approximately $100 per two-pack when Mylan acquired the marketing rights to EpiPen in 2007 to over $600 per two-pack by 2016. Had Mylan classified EpiPen as a branded drug, it would have been required to rebate an additional portion of the money it received from Medicaid sales as a result of these price increases.

CMS Informs Mylan That It Misclassified EpiPen

17. Beginning in 2013, CMS questioned Mylan's classification of EpiPen. Specifically, CMS emailed Mylan in September 2013 stating EpiPen "has an incorrect drug category in our . . . database, can you please verify the information with the FDA and update [the database] accordingly." In April 2014, CMS sent a similar email to Mylan. In response to both emails, Mylan attached a copy of the 1997 Letter, claiming that EpiPen was properly classified.

18. Internally at Mylan, however, doubts were raised about the appropriateness of classifying EpiPen as a generic drug under the MDRP and its reliance on the 1997 Letter. After learning that a competitive product was classified as branded, several Mylan executives reviewed the reason for the disparate classifications between EpiPen and the competitor's product.

19. As part of the review, a Mylan executive contacted Mylan's consultant to inquire about the disparate classifications. After obtaining information from the consultant, a Mylan employee emailed a different Mylan executive and stated that the generic classification was granted back in 1997, but "was basically just done as a result of a conversation two guys who were there at the time had" and that if the competitor had recently requested generic status from CMS "they would have been denied given today's market size and that ours was a loose interpretation to begin with."

20. In late 2014, CMS informed Mylan that it misclassified EpiPen. Specifically, at CMS's request, Mylan and CMS had a call on October 29, 2014 to discuss Mylan's EpiPen classification. Several Mylan executives and in-house counsel, including those involved in the preparation and review of Mylan's annual reports, as well as Mylan's external counsel, participated in the call with CMS. During the call, a CMS Division Director stated that EpiPen was misclassified and that the 1997 Letter should not be relied on as guidance. CMS requested that Mylan change the EpiPen classification in the CMS database. In the days following the call, Mylan executives and counsel met to discuss next steps and preliminarily analyzed the prospective financial impact of reclassifying EpiPen as a branded drug. Mylan, however, did not change its classification of EpiPen in submissions to CMS.

DOJ's Investigation of Mylan's EpiPen Classification

21. Within approximately one week of the CMS call, Mylan became aware of a DOJ civil investigation into its EpiPen classification. In November 2014, Mylan received a subpoena from DOJ, seeking documents concerning its classification of EpiPen. DOJ was investigating Mylan for potential violations of the False Claims Act for overcharging the government for EpiPen sales to Medicaid patients. The False Claims Act allows for trebled damages and penalties against a party who knowingly submits a false claim to the government. In response to the DOJ subpoena, Mylan cited the 1997 Letter and requested that DOJ close its investigation. Rather than close the investigation, DOJ insisted that Mylan respond to the subpoena, and over the next nine months, DOJ issued additional document subpoenas, served a civil investigative demand (*i.e.*, interrogatories) seeking information relating to the government's potential damages, and took testimony from a Mylan employee involved in government price reporting.

22. Mylan argued unsuccessfully on multiple occasions that DOJ should close the investigation. For example, in August 2015, Mylan's counsel made a presentation to DOJ, setting forth detailed arguments about why DOJ had no basis to bring any claims, including citing to the 1997 Letter. DOJ, however, rejected Mylan's request that it close the investigation, and requested that Mylan sign a tolling agreement that stopped the statute of limitations from running and thus would permit DOJ to charge Mylan for conduct spanning a longer time period. A senior member of Mylan's legal team signed the tolling agreement.

23. DOJ's investigation continued to move forward. In October 2015, Mylan produced an analysis to DOJ, showing that for just one quarter in 2015, potential damages owed to the government from Mylan's classifying EpiPen as a generic rather than a branded drug ranged from approximately $12 million to $42 million. Given that the estimates covered only

one quarter and False Claims Act damages could be trebled, Mylan knew or should have known that the total possible loss arising from DOJ's claims was exponentially higher than these amounts.

24. Throughout the following months, Mylan continued to produce documents and information to DOJ. In May 2016, DOJ requested a meeting to discuss the investigation, including potential resolution of the matter, and requested that Mylan provide additional information relevant to calculating damages in advance of the meeting. In response, in June 2016, Mylan provided additional data, including an estimate that non-trebled damages for the year 2015, alone, would range from about $114 to $260 million.

25. Mylan also consented to an extension of the tolling agreement in June 2016 and agreed to a meeting on July 12, 2016. Mylan executives, including those involved in the preparation and review of Mylan's financial statements, were involved in preparations for the DOJ meeting.

26. During the July 12, 2016 meeting, DOJ made a detailed presentation to Mylan, setting forth the bases for its claims. DOJ also provided damages estimates and indicated that it was prepared to sue Mylan unless Mylan made a settlement offer. On July 29, 2016, Mylan offered $50 million to settle DOJ's claims.

27. On August 3, DOJ rejected the $50 million offer and counter-offered at a significantly higher amount. The parties continued to negotiate until they reached a settlement in principle for $465 million in October 2016.

28. Mylan executives, including executives involved in the preparation and review of Mylan's financial statements, were aware of the progress of DOJ's investigation and settlement negotiations.

29. On October 7, 2016, Mylan, for the first time, disclosed DOJ's investigation and Mylan's liability resulting from its misclassification of EpiPen.

Mylan Failed to Timely Disclose or Accrue for Liability Relating to DOJ's Claims in its Financial Statements

30. Accounting Standard Codification 450 (ASC 450) codifies GAAP regarding "loss contingencies." A loss contingency is an existing condition, situation, or set of circumstances involving uncertainty as to a possible loss that will be resolved when one or more future events occurs or fails to occur. *See* ASC 450-20-20. Loss contingencies include (i) actual or possible claims and (ii) pending or threatened litigation. *See* ASC 450-20-05-10.

31. Under GAAP, an issuer must disclose a material loss contingency—such as a liability resulting from the claims that Mylan incorrectly classified EpiPen—if a loss is at least reasonably possible. A loss is considered "reasonably possible" when the chance of the future event or events occurring is more than remote but less than likely. A loss is considered "remote" when the chance of the future event or events occurring is slight. Additionally, an issuer must record an accrual for a material loss contingency, as a charge against income in its financial statements, if a loss is probable and reasonably estimable. *See* ASC 450-20-25-2. "Probable" means the future event or events is likely to occur. Regulation S-X requires financial statements in an issuer's filings with the SEC to comply with GAAP, and provides that financial statements filed with the SEC that are not prepared in accordance with GAAP are presumed to be misleading. *See* 17 C.F.R. § 210.4-01.

32. By at least the filing of its Form 10-Q for the third quarter of 2015, Mylan knew or should have known that the likelihood of a material loss relating to Mylan's EpiPen classification and DOJ investigation was reasonably possible. Because Mylan failed to disclose the nature of the contingency resulting from the investigation of whether Mylan incorrectly classified EpiPen in

violation of the False Claims Act, and its best estimate of the range of loss resulting from the contingency, Mylan's quarterly reports on Form 10-Q and annual report on Form 10-K from at least the third quarter of 2015 through the second quarter of 2016 were materially false and misleading.

33. Mylan's failure to timely disclose the DOJ investigation concerning EpiPen was inconsistent with Mylan's practice and treatment of other similar matters, including DOJ investigations of the pricing and classification of other Mylan drugs.

34. In addition, by at least the filing of the Form 10-Q for the second quarter of 2016, Mylan knew, or should have known, that a material loss resulting from the DOJ investigation and claims that Mylan incorrectly classified EpiPen was probable. Mylan also knew, or should have known, that a loss was reasonably estimable, as Mylan had sufficient information in its possession to estimate a range of losses. Therefore, Mylan should have accrued its best estimate of the loss (or, if it did not have a best estimate, the minimum amount of the loss within the estimated range of losses).

35. As a result of Mylan's failure to accrue for the loss, Mylan's reported earnings were materially overstated in the second quarter 2016 Form 10-Q and in its Form 8-K reporting results for the second quarter, both of which were filed on August 9, 2016.

36. Mylan's books, records and accounts were inaccurate because Mylan failed to timely disclose and accrue for the loss associated with the DOJ investigation.

37. Mylan also failed to devise and maintain a system of internal accounting controls sufficient to timely disclose and accrue for the loss associated with the DOJ investigation and permit preparation of financial statements in conformity with GAAP. For instance, although Mylan's controls required quarterly discussions of significant contingencies by its financial and legal teams, the controls failed to require material information be provided to the teams. Certain members of the

financial team evaluating the loss contingency relating to Mylan's EpiPen classification were not informed of some material developments concerning the progress of DOJ's investigation.

Mylan Made Misleading Risk Factor Disclosures in its 2014 and 2015 Annual Reports

38. Mylan also made misleading risk factor disclosures in its SEC filings. Specifically, in Mylan's 2014 and 2015 annual reports on Form 10-K, Mylan misleadingly stated that the company faced merely the risk that CMS may take the position that Mylan's submissions to CMS were incorrect.

39. Mylan's 2014 and 2015 annual reports stated, in connection with calculating and reporting payments to Medicaid, "a governmental authority may take a position contrary to a position we have taken." Mylan's 2015 annual report also stated, "We cannot assure you that our submissions will not be found by CMS . . . to be . . . incorrect."

40. This hypothetical phrasing created the impression that CMS had not yet taken a position on Mylan's classification of EpiPen. In fact, after CMS twice questioned Mylan in late 2013 and early 2014 about its EpiPen classification, CMS informed Mylan in October 2014 that its classification of EpiPen as a generic drug was incorrect and asked Mylan to correct the classification in the CMS system.

41. As a result, Mylan knew, or should have known, that its Risk Factor disclosures in its 2014 and 2015 annual reports on Form 10-K were materially misleading.

FIRST CLAIM FOR RELIEF

Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act

42. Paragraphs 1 through 41 are realleged and incorporated by reference herein.

43. By engaging in the conduct alleged above, Mylan, directly or indirectly, in the offer or sale of securities, by use of any means or instruments of transportation or communication in interstate commerce or by use of the mails,

a. obtained money or property by means of untrue statements of material fact or by omitting to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

b. engaged in transactions, practices, or courses of business that operated or would operate as a fraud or deceit upon purchasers.

44. By reason of the foregoing, Mylan violated, and unless restrained and enjoined will violate in the future, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and 77q(a)(3].

SECOND CLAIM FOR RELIEF

Violations of Exchange Act Section 13(a) and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13

45. Paragraphs 1 through 41 are realleged and incorporated by reference herein.

46. Mylan has at all relevant times been an issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78*l*].

47. Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 13a-1, 13a-11, and 13a-13 thereunder [17 C.F.R. §§ 240.13a-1, 240.13a-11 and 240.13a-13] require issuers of registered securities to file with the SEC factually accurate annual reports (on Form 10-K), quarterly reports (on Form 10-Q), and current reports (on Form 8-K). Exchange Act Rule 12b-20 [17 C.F.R. § 240.12b-20] provides that, in addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they were made, not misleading.

48. Based on the conduct alleged above, Mylan violated, and unless restrained and enjoined will violate in the future, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§ 240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13].

THIRD CLAIM FOR RELIEF

Violations of Exchange Act Section 13(b)(2)(A)

49. Paragraphs 1 through 41 are realleged and incorporated by reference herein.

50. By engaging in the conduct alleged above, Mylan failed to make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions of the company and dispositions of its assets.

51. By reason of the foregoing, Mylan violated, and unless restrained and enjoined, will violate in the future, Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].

FOURTH CLAIM FOR RELIEF

Violations of Exchange Act Section 13(b)(2)(B)

52. Paragraphs 1 through 41 are realleged and incorporated by reference herein.

53. By engaging in the conduct alleged above, Mylan failed to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP.

54. By reason of the foregoing, Mylan violated, and unless restrained and enjoined will violate in the future, Section 13(b)(2)(B) of the Exchange Act [15 U.S.C. § 78m(b)(2)(B)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that the Court enter a final judgment:

A. Permanently enjoining Mylan from future violations of Sections 17(a)(2) and (a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and 77q(a)(3)]; Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a), 78m(b)(2)(A), and 78m(b)(2)(B)]; and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-1, 240.13a-11, and 240.13a-13];

B. Ordering that Mylan pay civil money penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d) of the Exchange Act [15 U.S.C. § 78u(d)] in an amount to be determined by the Court; and

C. Retaining jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

Date: September 27, 2019

/s/

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