UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Mylan N.V. Securities Litigation	Case No. 1:16-CV-07926 (JPO) **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF SECURITIES LAWS** **JURY TRIAL DEMANDED**

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Lead Plaintiffs Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd. (collectively, the "Israeli Investor Group") and Dan Kleinerman (together with the Israeli Investor Group, "Plaintiffs" or "Lead Plaintiffs") on behalf of a class of all purchasers of Mylan N.V. common stock made on the NASDAQ (the "NASDAQ Investor Class"), and the Israeli Investor Group on behalf of a class of all purchasers of Mylan N.V. common stock made on the Tel Aviv Stock Exchange ("TASE") (the "TASE Investor Class"), allege the following by and through their attorneys and on behalf of all other persons and entities similarly situated. All of the following allegations are made upon information and belief, except those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Mylan N.V. ("Mylan" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Mylan; (c) review of complaints filed in other actions against Mylan and its executives; (d) review of other publicly available information concerning Mylan; and (e) interviews with former employees of Mylan.

I. INTRODUCTION

1. This is a class action (the "Action") on behalf of two classes of persons or entities that acquired the securities of Mylan N.V. and/or Mylan N.V.'s predecessor, Mylan Inc., between February 21, 2012 and January 29, 2017, both dates inclusive (the "Class Period"). The Action seeks to recover damages and to obtain other remedies for Defendants' violations of the Securities Exchange Act of 1934 (the "Exchange Act") and of the Israel Securities Law of 1968 (the "Israel Securities Law").

2. Mylan, together with its subsidiaries, develops, licenses, manufactures, markets, and distributes brand-name and generic pharmaceuticals worldwide. Mylan manufactures and sells, among other products, the EpiPen Auto-Injector® and EpiPen Jr Auto-Injector® (collectively, the "EpiPen"), a branded drug that allows the user to autoinject a measured dose of epinephrine to treat anaphylaxis, a life-threatening emergency to which one in thirteen children is susceptible. Mylan also manufactures and sells the following generic drugs, among others: albuterol sulfate, used to treat asthma and other lung conditions; benazepril, used to treat high blood pressure; clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness; divalproex, used to treat certain types of seizures and migraines; doxycycline hyclate delayed release ("Doxy DR"), a tetracycline antibiotic used to treat a wide range of bacterial infections, including severe respiratory infections and anthrax; and propranolol, a beta-blocker used to treat and prevent heart attack and other heart and circulatory conditions.

3. Mylan is a dishonest company. Over the past two decades, in over a dozen matters, Mylan has repeatedly been investigated by the FTC, the DOJ and the SEC, and sued by private litigants, for fraudulently overcharging Medicaid for its drug purchases, for illegal price manipulation, for entering into illegal anticompetitive agreements, and for other wrongful conduct. These wrongs by Mylan are chronic—Mylan has repeated the same misdeeds time and again. And while the wrongs addressed in this Action are only the most recent examples of Mylan's proven history of such misdeeds, they are perhaps the most serious. Through the conduct described in this complaint, Mylan made lifesaving drugs less available to children, the elderly, and other ordinary Americans who struggle to afford these drugs.

4. Plaintiffs bring this Action because, during the Class Period, Mylan misled Plaintiffs about a course of conduct intended to cheat Medicaid (the U.S. low-income healthcare program) out of its rightful rebates for EpiPen purchases, about anticompetitive agreements it extracted from competitors and grade schools that allowed it to inflate the price of EpiPen astronomically, beyond the reach of many consumers, and about a scheme to inflate the prices of critical generic drugs by over 1000% by engaging in numerous anticompetitive activities. In particular: (1) Mylan systematically and knowingly misclassified the EpiPen as a generic drug in order to overcharge Medicaid by hundreds of millions of dollars for its purchases of this life-saving device for Medicaid recipients; (2) Mylan entered into anticompetitive agreements in order to be able to inflate the price of the EpiPen, including a "pay-for-delay" agreement to delay the entry into the market of a generic competitor of the EpiPen, which would have lowered its price, and exclusive dealing agreements with schools requiring them not to purchase products competitive with the EpiPen; and (3) Mylan entered into, and maintained, anticompetitive agreements with its "competitors" to allocate the market for Doxy DR, and to fix the prices of generic albuterol sulfate, benazepril, clomipramine, divalproex, and propranolol at stratospheric levels.

5. *First*, as soon as Mylan acquired the rights to market the EpiPen, Mylan knowingly misclassified the EpiPen for the purposes of the Medicaid Drug Rebate Program ("MDRP"). Under the MDRP, drug companies enter a contract with the agency that administers Medicaid, the Centers for Medicare & Medicaid Services ("CMS"), under which they agree to give CMS rebates on their drugs—rebates that represent bulk discounts on CMS's massive drug purchases for Medicaid. Federal law requires companies to give Medicaid a lower rebate for generic drugs, which drug companies already sell at close to cost, than for

brand name or patented drugs, which drug companies usually sell at a significant markup. The responsibility of categorizing drugs correctly as generic or brand name drugs lies with the drug companies.

6. This categorization is remarkably straightforward, and follows unambiguously from laws and regulations that have remained essentially unchanged since 1990, when the MDRP was first implemented—if the FDA approved a drug under a new drug application ("NDA") (which is used for new, usually patented drugs), that drug is a brand name drug for the purposes of the MDRP, and if the drug was not approved under an NDA, the drug is a generic drug.

7. There is not, and never has been, any question about how the EpiPen should be classified. Even a layperson wholly unfamiliar with laws and regulations regarding classification of the EpiPen would know that the EpiPen is a brand-name drug and not a generic—it is an extremely expensive, branded and patented product that bears a trademarked logo rather than an active ingredient on its label—it is nothing like the cheap generic medication Congress expected already to be sold at close to cost. But just as importantly, a layperson also would have no trouble classifying the drug under Medicaid's laws and regulations—all he or she would need to do would be to look up the EpiPen on the FDA's website and note that it was approved under an NDA in order to classify the drug as a brand name drug for the purposes of the MDRP. No exceptions to this rule existed in the laws and regulations governing classification of drugs for the purposes of the MDRP.

8. Mylan is not a layperson; rather, Mylan has an army of highly sophisticated lawyers. These lawyers were capable of doing what a layperson could do—of classifying the

EpiPen correctly as a brand-name drug. Instead, Mylan knowingly misclassified the EpiPen as a generic, from when it first acquired rights to the drug in 2007 to the present.

9. Indeed, before the Class Period, CMS expressly notified Mylan that the EpiPen was misclassified, as the Acting Administrator Andrew M. Slavitt has confirmed in correspondence with the U.S. Senate. In early 2009, the Inspector General of the Department of Health and Human Services expressly told CMS that the EpiPen was misclassified for the purposes of the MDRP. Thereafter, on multiple occasions CMS expressly notified Mylan that the EpiPen was misclassified. As Slavitt stated in an October 5, 2016 letter to Senator Ron Wyden, "CMS has, on multiple occasions . . . expressly told Mylan that the product [EpiPen] is incorrectly classified." As detailed below, the most reasonable inference to be drawn about the timing of this notification is that CMS was not completely derelict in its duties and notified Mylan of this misclassification within three years at the latest upon receiving notice from the Inspector General.

10. Mylan repeatedly misrepresented to investors the legal situation it faced as a result of its blatant misclassification of the EpiPen for the purposes of the MDRP. In its SEC filings, Mylan repeatedly created the misimpression that the classification scheme for the purposes of the MDRP was highly complex, involved subjective judgments, and contained ambiguities. In fact, as Mylan admitted in other sections of its SEC filings, the classification scheme was simple and consisted of bright-line rules. Mylan created this misimpression because it knew, or recklessly disregarded, that its classification of the EpiPen was simply wrong.

11. Separately, Mylan also repeatedly misrepresented that there was no investigation into its classification of the EpiPen when in fact the Department of Justice launched just such an investigation in November 2014. Mylan is independently liable for these misrepresentations.

12. *Second*, Mylan also engaged in anticompetitive conduct during the Class Period in an attempt to prevent or delay competition against the EpiPen. In particular: (1) in settling its patent infringement suit against Teva Pharmaceuticals ("Teva") relating to the patents covering the EpiPen, Mylan, in concert with Meridian Medical Technologies and King Pharmaceuticals, agreed to give Teva a "reverse payment" in exchange for Teva's agreeing to delay introducing its generic epinephrine autoinjector into the market until 2015, in a so-called "pay-for-delay" scheme; and (2) Mylan entered into exclusive dealing agreements with schools under which Mylan agreed to sell the EpiPen to these schools at a discount in exchange for an agreement by the schools not to purchase any product competitive with the EpiPen.

13. *Third,* beginning in 2013 at the latest and continuing into the present, Mylan entered into anticompetitive agreements with its competitors in the generic drug market. In particular, Mylan agreed with its competitors to allocate the market for Doxy DR so that the drug companies, including Mylan, that manufactured Doxy DR would not compete against one another for major customers and so would not bring down the price of Doxy DR through competitive bids. Mylan also agreed with drug companies to fix the price of certain generic drugs, including albuterol sulfate, benazepril, clomipramine, divalproex, and propranolol (the "Price-Fixed Drugs").

14. The evidence that Mylan engaged in this anticompetitive conduct is overwhelming. On December 14, 2016, the attorneys general of twenty states (the "States") filed a joint complaint against Mylan that was the product of a years-long investigation. In the

complaint, the States detail the fruits of their investigation and tell the story, with great detail and relying on documentation, of how Mylan agreed to allocate the market for Doxy DR with its competitors. Mylan expressly agreed not to compete with other companies for the business of particular wholesalers of Doxy DR, and for years, Mylan acted in accordance with that agreement.

15. The evidence that Mylan colluded to fix the price of the Price-Fixed Drugs is likewise clear. The average prices of these drugs in the United States moved in near-perfect unison during the period of the conspiracy, and the prices of these drugs increased suddenly and simultaneously at each drug company at or near the start of that period. The price increases were exponential—the prices of multiple drugs, including for example clomipramine and propranolol increased suddenly by over 1000%. No other explanation for these sudden, synchronized price increases exists—there was no supply shortage or sudden increase in demand for these drugs during this period. Moreover, the market for generic drugs is highly susceptible to collusion for a number of reasons detailed below. For example, the markets for the Price-Fixed Drugs are dominated by only a few companies, and this market concentration makes collusion easy. The extreme price increases caused by this generic drug price-fixing cartel, in which Mylan is an active and important player, imposed, and continue to impose, a searingly unfair burden on nearly all residents of the United States, including children and the elderly, who, without exaggeration, rely on affordable generic drugs for their quality of life, and in some cases, their survival.

16. Mylan misled investors about the competition it faced and about the validity of its sales figures. Mylan repeatedly stated to investors that the market for generic drugs was highly competitive. In fact, the market for at least some of the generic drugs Mylan sold was

collusive, and lacked any real competition. Mylan's sales figures and other measures of Mylan's financial performance were also misleading. Based on Mylan's false and misleading statements, investors reasonably assumed that Mylan's sales figures relating to its generic drugs were an accurate representation of the success of Mylan's products in a competitive market. In fact, those sales figures were inflated as a result of Mylan's anti-competitive conduct, and did not reflect the sales Mylan would have been able to achieve absent its market allocation and price-fixing activity. Reasonable investors would have wanted to know this difference in the basis for Mylan's sales—because Mylan's sales figures were inflated through its participation in an anticompetitive cartel, these figures were susceptible to being deflated if and when the cartel were to break.

17. When these frauds concealed by Mylan became known to the investing public, Mylan's stock dropped precipitously. In late August 2016, a news article detailed how Mylan had increased the price of the EpiPen over 500%, revealing the effects of Mylan's anticompetitive conduct and causing public outcry. U.S. Congresspersons then called on Congress and the FTC to investigate Mylan for anticompetitive conduct relating to the EpiPen. Upon this news and other related revelations, Mylan stock fell $6.17, or 12.51% between August 19 and August 24, 2016. When the FTC announced on January 30, 2017 that it was investigating Mylan, Mylan's stock fell even further.

18. As more information about Mylan's frauds was revealed to the public, Mylan's stock price continued to fall. On September 2, 2016 *Inside Health Policy* published an article revealing that CMS had informed Mylan that the Company had incorrectly classified EpiPen as a generic under the MDRP, and that Congress was asking CMS and Mylan for an explanation of the classification of the EpiPen as a generic drug. On October 5, 2016, Bloomberg published an

article revealing CMS's response to the Congressional inquiry and its confirmation that Mylan had incorrectly classified the EpiPen for years. On this news, Mylan's share price fell $1.95, or 4.65%, to close at $39.97 on September 2, 2016, and fell $1.19, or 3.13%, to close at $36.84 on October 6, 2016.

19. On November 3, 2016, Bloomberg News reported that U.S. prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion. On December 14, 2016, Bloomberg reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, were "preparing to plead guilty to price-fixing charges," in a scheme that involved unnamed executives from Mylan. On January 10, 2017, The Philadelphia Inquirer published an article stating that Glazer and Malek had admitted to the charges of conspiring to manipulate prices of generic drugs. On this news, shares of Mylan fell $2.53 or 6.9% on November 3, 2016, $0.61 or 1.6% on December 14, 2016 and $2.18 or 5.6% between January 10 and January 12, 2017.

20. In total, upon the disclosures of Defendant's wrongful acts and omissions, the market value of Mylan has plummeted by more than $5.5 billion. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Mylan's securities, Plaintiffs and other members of the Classes suffered significant losses and damages.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to §§ 10(b), 14(e) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78n(e) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. The Court also has supplement jurisdiction over claims arising under Israeli Law pursuant to 28 U.S.C. §§ 1367.

23. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act and 28 U.S.C. §1391(b). Mylan N.V.'s stock trades on the NASDAQ-GS, located within this Judicial District.

24. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

25. Plaintiffs Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd., as set forth in the certifications attached as Exhibit B to the Declaration of Jeremy A. Lieberman (Dkt. 20), incorporated herein by reference, and Dan Kleinerman, as set forth in the certification attached as Exhibit B to the Declaration of Daniel S. Sommers (Dkt. 13), incorporated herein by reference, acquired Mylan securities on the NASDAQ at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures. Moreover, the members of the Israeli Investor Group purchased Mylan securities on the Tel Aviv Stock Exchange ("TASE") between November 4, 2015 and the end of the Class Period and were similarly damaged upon the revelation of the alleged corrective disclosures.

26. Defendant Mylan N.V. is incorporated in the Netherlands. Mylan N.V.'s principal executive offices are located at Building 4, Trident Place, Hertfordshire AL10 9UL,

United Kingdom. Mylan, together with its subsidiaries, develops, licenses, manufactures, markets, and distributes generic, and specialty pharmaceuticals worldwide. The Company provides generic pharmaceutical products in tablet, capsule, injectable, transdermal patch, gel, cream, or ointment forms, as well as active pharmaceutical ingredients. Among other products, Mylan markets and sells the EpiPen, a branded device for injecting a measured dose of epinephrine by means of auto-injector technology to treat severe allergic reactions. Mylan Inc. is an indirect wholly owned subsidiary of Mylan N.V. Prior to February 27, 2015, Mylan Inc. preceded Mylan N.V. as the SEC registrant. In early 2015, Mylan Inc.'s business was reorganized under Mylan N.V. and led by the former officers and directors of Mylan Inc. On February 27, 2015, Mylan N.V. succeeded Mylan Inc. as the SEC registrant. Mylan N.V.'s common stock began trading on the Nasdaq Global Select Market ("NASDAQ-GS") on March 2, 2015 under the ticker symbol "MYL." Mylan N.V.'s stock began trading on the Tel Aviv Stock Exchange ("TASE") on November 4, 2015, also under the ticker symbol "MYL."

27. Defendant Mylan Inc. is incorporated in Pennsylvania. Mylan Inc.'s principal executive offices are located at 405 Lexington Avenue, Floor 52, New York, New York 10174.

28. Defendant Heather Bresch ("Bresch") has served as the Company's Chief Executive Officer ("CEO") since January 2012. From 2002 to 2005, Bresch served as Mylan's Director of Government Relations.

29. Defendant Robert J. Coury ("Coury") served as the Company's CEO from September 2002 to January 2012.

30. Defendant Paul B. Campbell ("Campbell") has served as the Company's Chief Accounting Officer since May 2015.

31. Defendant Kenneth S. Parks ("Parks") has served as the Company's Chief Financial Officer ("CFO") since June 2016.

32. Defendant John D. Sheehan ("Sheehan") served as the Company's CFO from April 2010 to April 2016.

IV. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS OVERCHARGING MEDICAID FOR EPIPENS AND BY FAILING TO DISCLOSE THAT MYLAN WAS BEING INVESTIGATED FOR ITS EPIPEN CLASSIFICATION

A. The Importance of EpiPen to Mylan's Business

33. Ever since Mylan first acquired the EpiPen in 2007, the EpiPen has been enormously important to Mylan's business. As illustrated in the following table, during the Class Period, the EpiPen was responsible for between 28% and 95% of Mylan's operating profits—*i.e.*, profit earned from Mylan's normal, core business operations.

Operating Profit by Year (millions USD)[1]					
	2012	**2013**	**2014**	**2015**	**2016**
EpiPen	306	393	525	498	671
Total Mylan	1,109	1,135	1,352	1,460	701
% from EpiPen	27.59%	34.63%	38.83%	34.11%	95.64%

34. The EpiPen's paramount importance to Mylan is also reflected in analyst reports covering the company, which, throughout the Class Period, devoted significant attention to the EpiPen and routinely tied Mylan's overall fortunes to the EpiPen.

35. For example, in a report dated August 24, 2016, RBC Capital Markets analyst Randall Stanicky noted that, "the importance of [EpiPen] to [Mylan's] P&L growth over the last

[1] EpiPen operating profits are taken from a September 2016 SEC filing made by Mylan specifically for the purpose of providing profitability information about the EpiPen, after Mylan gave testimony on that topic to Congress. That filing explained that "Mylan does not regularly provide profitability analyses for individual products and does not intend in the future to provide product level profitabilty [*sic*] analysis for EpiPen or to update this analysis." The figure for 2016 is an estimated figure. Total Mylan operating profits are taken from Mylan's Form 10-Ks, where they are reported as "Earnings from operations."

several years has been well understood," and that "EPIPEN has been an important growth driver for MYL the last several years."[2] JPMorgan analyst Chris Schott similarly noted in an October 4, 2016 report that "Epipen is Mylan's largest product at >$1bn in sales."[3] In fact, Morningstar's mere four-sentence profile of the company highlights the EpiPen by name, noting that after revenue from generics, "[r]emaining sales come from a handful of branded products, primarily the epinephrine injector EpiPen." The EpiPen is the only drug specifically mentioned by name. Indeed, in an October 18, 2016 report, Morningstar analyst Michael Zbinovec wrote that "Mylan's specialty drug franchise is essentially comprised entirely of EpiPen."[4]

36. EpiPen sales were also critically important to Mylan's quarterly earnings results and Mylan's ability to meet analyst expectations. For example, in a report dated February 11, 2016, BTIG analyst Timothy Chiang wrote that Mylan was "in need of EpiPen after weak Q4," to make up for a weaker than expected fourth quarter in 2015.[5] A few quarters later, when the Company beat expectations, analysts attributed the success to the EpiPen. For instance, in an August 9, 2016 report, Morgan Stanley analyst David Risinger noted that "Epipen drove EPS slightly above" expectations.[6] Similarly, in an August 10, 2016 report titled "Epipen takes the

[2] Randal Stanicky, Matthew Won & Ashley Ryu, *Our thoughts on negative EPIPEN pricing "headline": Direct read to MYL but also implications for TEVA and IPXL*, RBC Capital Markets (Aug. 24, 2016).

[3] Chris Schott, Dana Flanders & Aditi Singhania, *Mylan NV: Updating Estimates for Epipen; Remain Cautious In NT But Valuation Offers Compelling LT Entry Point*, J.P.Morgan (Oct. 4, 2016).

[4] Michael Waterhouse & Damien Conover, *Mylan's EpiPen pricing blowback doesn't dramatically alter the company's significant challenges*, Morningstar (Oct. 18, 2016); and Michael Zbinovec, *Mylan is digesting Meda while facing EpiPen headline risk*, Morningstar (Oct. 18, 2016).

[5] Timothy Chiang & Ben Shim, *Mylan N.V.: In Need of Epipen After Weak Q4; Net Model w/ Meda Suggests Much Needed Accretion is Possible; Buy*, BTIG (Feb. 11, 2016).

[6] David Risinger, et al., *Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

driver's seat," Barclays analyst Douglas D. Tsao concurred that "Epipen was clearly the big driver of 2Q results."[7]

37. EpiPen sales also drove analysts' ratings and evaluations of Mylan's financial prospects. Numerous analysts equated risks to the EpiPen business with risks to their evaluations of Mylan as a whole. For instance, JPMorgan analysts included "generic competition for Epipen" as one of three "[r]isks to the downside" for its overall rating of and price target for Mylan, in a March 1, 2016 report, an August 10, 2016 report, an October 4, 2016 report, and an October 10, 2016 report.[8] Morgan Stanley analysts also repeatedly included "FDA approval of pharmacist-substitutable generic Epipen" as the first risk listed in a section titled "Risks to Achieving Price Target," including in a February 12, 2016 report and again in an August 9, 2016 report.[9] BTIG analysts similarly stated that the one of the three "key risks" to its evaluation of Mylan were "Epipen revenues not meeting estimates," in a January 21, 2016 report and again in an August 29, 2016 report.[10]

38. During the Class Period, Mylan's sales of EpiPen through Medicaid accounted for a very significant amount of Mylan's total sales of the EpiPen. In an October 10, 2016

[7] Douglas D. Tsao & Morgan Williams, *Mylan Inc.: Epipen takes the driver's seat*, Barclays (Aug. 10, 2016).

[8] Chris Schott, et al., *MYL/TEVA: Positive Epipen News Supports EPS Upside for MYL*, J.P.Morgan (March 1, 2016); Chris Schott, et al., *Mylan NV: Solid Qtr Lead by Epipen; Long-Term Growth Trajectory Remains Intact*, J.P.Morgan (Aug. 10, 2016); Chris Schott, et al., *Mylan NV: Updating Estimates for Epipen; Remain Cautious in NT But Variation Offers Compelling LT Entry Point*, J.P.Morgan (Oct. 4, 2016); and Chris Schott, et al., *Mylan NV: Epipen Rebate Settlement and Updated Guidance A Positive*, J.P.Morgan (Oct. 10, 2016).

[9] David Risinger, et al., *Mylan: Epipen 4Q sales hurt by inventory workdown, not price adjustments as we hypothesized*, Morgan Stanley (Feb. 12, 2016); and David Risinger, et al., *Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

[10] Timothy Chiang & Ben Shim, *Mylan N.V.: Upping Estimates to Reflect Higher Epipen Sales; Buy*, BTIG (Jan. 21, 2016); and Timothy Chiang, *Mylan N.V.: MYL to Launch Authorized Generic Version of Epipen*, BTIG (Aug. 29, 2016).

report, UBS analyst Marc Goodman estimated that "Medicaid spending on EpiPen is ~35% of [Mylan's total] 2015 [EpiPen] sales."[11]

39. As Mylan's sales of EpiPen constituted a massive part of Mylan's business, and as sales of EpiPen through Medicaid accounted for a very significant part of Mylan's EpiPen sales, Mylan's classification of the EpiPen for the purposes of the Medicaid Drug Rebate Program was highly consequential to the Company.

B. Legal Classification of Drugs for the Purposes of the Medicaid Drug Rebate Program

40. Medicaid is a U.S. government insurance program for persons whose income and resources are insufficient to pay for health care. Jointly funded by the state and federal governments, Medicaid is the largest source of funding for medical and health-related services for Americans with low income.

41. The Medicaid Drug Rebate Program ("MDRP"), which was created as part of the Omnibus Budget Reconciliation Act of 1990 (the "1990 Act"), requires a drug manufacturer to enter into, and have in effect, a rebate agreement with the Centers for Medicare & Medicaid Services ("CMS") in order to receive state Medicaid coverage of the manufacturer's drugs. The rebate agreement imposes reporting and rebating requirements on the drug manufacturers. Manufacturers are required to identify all their covered outpatient drugs to CMS and provide CMS pricing data on those drugs. Manufacturers are then responsible for paying a rebate for their covered drugs that have been purchased and dispensed under state Medicaid plans. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the

[11] Marc Goodman, *Mylan Inc.: We're Still Constructive on MYL*, UBS (Oct. 10, 2016). This estimate relied on the October 5, 2016 letter to Senator Ron Wyden from CMS Acting Administrator Andrew M. Slavitt, which reported that total Medicaid spending on EpiPen from 2011 to 2015 was $960 million, with $253 million spent in 2014 and $365 million in 2015.

states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program.

42. The purpose of the MDRP is to ensure that pharmaceutical companies grant appropriate bulk-discounts to government purchases of prescription drugs that are commensurate with the massive volume of these purchases. CMS, which is part of the Department of Health and Human Services (HHS), administers Medicaid in partnership with state governments.

43. However, in creating the MDRP, lawmakers recognized that generic drugs, which generally face significant competition from competitors, are less "overpriced" than brand drugs, which are usually patented and unique. Whereas competition usually will bring down the prices of generic drugs to close to the cost to the manufacturers of producing those drugs, market forces will not similarly bring down the price of brand drugs, which are patented or otherwise face no direct competition. Accordingly, lawmakers required drug manufacturers that participate in MDRP to provide a greater rebate for patented drugs and drugs that otherwise face no competition than for generic drugs, which the government already buys at close-to-cost prices.

44. Drug manufacturers are responsible for correctly classifying their drugs and paying the correct rebate amounts for their drugs under the MDRP. This classification is not complicated. From the very beginning of the MDRP in 1990 to the present, the enabling statute and regulations governing the MDRP have only ever allowed three possible classifications for a drug like the EpiPen for the purposes of the MDRP: (1) a single source drug ("S" drug); (2) an innovator multiple source drug ("I" drug); and (3) a noninnovator multiple source drug ("N"

drug).[12] The rule for classifying drugs under the 1990 Act, which has not changed since its enactment, is simple and unambiguous: drugs that are approved under an original new drug application ("NDA") must be classified as either "S" or "I" drugs, while drugs that are not approved under an original new drug application (such as those approved under an abbreviated new drug application) must be classified as "N" drugs."[13] An NDA is the application drug manufacturers use to obtain approval to market a new drug, which is generally subject to a patent, whereas an ANDA is the application generic drug manufacturers use to seek approval to market a generic version of a drug already introduced to the market after gaining approval under an original new drug application. Therefore, under the 1990 Act, all drugs that are approved under NDAs (which are generally patented brand drugs) must be classified as S or I drugs, whereas all drugs that are approved under ANDAs (which are generic drugs) are classified as N drugs. No exceptions to this rule are present in the language or intent of the 1990 Act.

45. As for classifying drugs approved under NDAs as either S or I drugs, a drug approved under an NDA must be classified as an I drug if the FDA has determined that the drug has at least one other "therapeutic equivalent," *i.e.*, another drug available in the United States that offers the same therapeutic benefits as the drug being classified. However, this distinction is insignificant for the purposes of the determining the rebate amount owed under the MDRP—all S or I drugs are subject to the same higher rebate calculations than that to which N drugs are subject.

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[12] 42 U.S.C. § 1396r–8(k)(7).

[13] In the language of the statute, a single source drug or S drug is "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration . . . ." 42 U.S.C. § 1396r–8 (k)(7). An innovator multiple source drug or I drug is "a multiple source drug [*i.e.*, a drug that has at least one other "therapeutically equivalent" drug] that was originally marketed under an original new drug application approved by the Food and Drug Administration. *Id*. A noninnovator multiple source drug or N drug is "a multiple source drug that is not an innovator multiple source drug [*i.e.*, is not a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration]." *Id*.

46. While under the 1990 Act, a drug marketer need only know whether or not a drug was approved for marketing under an NDA in order to classify that drug correctly for the purposes of rebates under the MDRP, a second unambiguous, bright line rule in the statutory language also makes classification simple: ***in no event*** can a drug that does not face competition from any therapeutically equivalent drug be classified as a generic or N drug; that is, if a drug is the only drug on the market that, according to the FDA, offers the same therapeutic benefits that it does, that drug cannot be a generic or N drug. Under 42 CFR 447.509, as relevant for the purposes of this complaint, for a drug to be classified as an N drug there must be "at least one other drug product which [. . .] [i]s rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations')." That is, under the 1990 Act, a drug has a therapeutic equivalent if such an equivalent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." The Orange Book is not hard to find—it has been available in the FDA's public reading room since 1990, and has been available on the FDA's website, in searchable form, since at least 2007.[14]

47. On October 1, 2007, the first regulations promulgated pursuant to the 1990 Act, 42 CFR 447.500 et seq., became effective (the "2007 Regulations"). These regulations largely adopted the statutory definitions of S, I and N drugs, and for the purposes of this complaint, made only one small change to the classification scheme detailed in the 1990 Act: S or I drugs include, in addition to all drugs approved under an NDA, drugs "approved under a biologics license application (BLA), product license application (PLA), establishment license application

[14] The current version of the Orange Book may be found at http://www.fda.gov/cder/orange/default.htm.

(ELA), or antibiotic drug application (ADA)."[15] These applications are used only for certain medical products, such as vaccines, antibiotics, certain antibodies, blood and blood by-products, tissue and cellular products; these applications are not used for drugs for the treatment of anaphylaxis. Accordingly, under the 2007 Regulations, the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remained unchanged; the 2007 Regulations simply expanded the bright line rule by making clear that in addition to all drugs approved under NDAs, all drugs approved under BLAs, PLAs, ELAs and ADA must also be classified as S or I drugs.

48. On at least two occasions since 2007, CMS has issued guidance regarding the proper classification of drugs under the MDRP. Given that the classification of drugs for the MDRP is extremely straightforward, in both instances, CMS's guidance constituted exactly one paragraph. On January 5, 2010, CMS informed drug companies in Manufacturer Release No. 80:[16]

> In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).

49. On September 12, 2014, CMS repeated the same guidance quoted above in Manufacturer Release No. 91:

> In general, covered outpatient drugs that are approved under a new drug application (NDA) should be reported to CMS as either "S" or "I" drugs, while drugs approved under an abbreviated new drug application (ANDA) should be reported to CMS as "N" drugs.[17]

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[15] 42 CFR § 447.502 (2007)

[16] Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 80* (Jan. 5, 2010), at 3.

[17] Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91* (Sept. 12, 2014), at 3.

50. The "in general" language in the above-quoted paragraphs is superfluous. No exception to the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP exists in the statutory language of the 1990 Act or in the 2007 Regulations.[18]

51. In February 2016, CMS published a Final Rule modifying slightly the definitions of S, I and N drugs found in the 2007 Regulations (the "Final Rule").[19] The Final Rule became effective April 1, 2016 (the "2016 Regulations").[20] Under the 2016 Regulations, the basic bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remains unchanged, but the 2016 Regulations introduced a bright line exception to the rule: an NDA need not be classified as an S or I drug if and only if, following the effective date of the 2016 Regulations (April 1, 2016), a drug marketer requests that CMS treat a drug approved under an NDA as if it were approved under an ANDA for the purposes of the MDRP, and CMS then expressly determines that a "narrow exception" applies to that drug and grants the drug manufacturer leave to classify the drug as an N drug.[21] Notably, certain classes of drugs are categorically excluded from this "narrow exception." In guidance published alongside the Final Rule, CMS stated, "the narrow exception will not be considered applicable to drugs . . . that received patent protection or statutory exclusivity."[22]

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[18] Moreover, industry practice and the practice of CMS is to classify a drug delivery product filed under a new drug application as an S or I drug, even if any patents covering the substance delivered by the product have expired.

[19] Final Rule, 81 Fed. Reg. 5170 (Feb. 1, 2016).

[20] 42 CFR § 447.509 (2016).

[21] In the language of the 2016 Regulations, in the definitions of S and I drugs, "an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies."

[22] 81 Fed. Reg. 5170, 5191 (Feb. 1, 2016). As explained *infra*, this "narrow exception" cannot apply to Mylan's classifications during the Class Period because: (1) a request for the exception could only be made after the effective date of the 2016 Regulations; (2) to date Mylan has not requested that this "narrow exception" apply to the EpiPen; and (3) in any event, the exception cannot apply to the EpiPen because the EpiPen has "received patent protection."

52. In summary, from the beginning of the MDRP in 1990 until April 1, 2016, applicable law and regulations required all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP. After April 1, 2016, applicable regulations require all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP, unless CMS finds after April 1, 2016 that a narrow exception applies, and a narrow exception will never apply to drugs that have received patent protection. Moreover, at no point have applicable laws or regulations permitted a drug that does not face competition from any therapeutically equivalent drug to be classified as a generic or N drug.

53. The difference in rebate amounts owed for generic and non-generic drugs is significant. In general, under current regulations, drug manufacturers must pay CMS a rebate of 23.1% of the average manufacturer price of patented drug classified as an S or I drug, yet the manufacturer need pay a rebate of only 13% of the average manufacturer price of a generic or N drug.[23] A drug manufacturer reaps a substantial financial benefit if it classifies a drug as a generic or N drug for the purposes of the MDRP. Indeed, as explained below, Mylan was able to overcharge Medicaid by over $700 million as a result of its misclassification of the EpiPen as a generic drug.

C. History of Classifications of EpiPen for the Purposes of the Medicaid Drug Rebate Program

54. The emergency drug autoinjector pen was first invented in the mid-1970s at Survival Technology in Bethesda, Maryland by Sheldon Kaplan. Initially, his device was called the ComboPen, and was purchased by the military for soldiers to use to autoinject nerve agent antidote in the event of chemical warfare. Kaplan and others eventually recognized that the same autoinjection technology, covered by U.S. Patent No. 4031893, among others, could be

[23] 42 CFR § 447.509 (2016).

used to deliver epinephrine to treat anaphylaxis, and developed the EpiPen for that purpose. In the late 1980s, Survival Technology submitted the EpiPen to the FDA for approval under an NDA, and on December 22, 1987, the FDA approved the NDA, Number 019430, and permitted the EpiPen to be marketed in the United States.

55. When the EpiPen first was reported to CMS for the purposes of the MDRP, the EpiPen was classified accurately as a non-generic S drug.[24] As explained above, under the 1990 Act, all drugs that are approved under NDAs must be classified as S or I drugs. The EpiPen was approved under an NDA, so Survival Technology had to classify it as an S or I drug. Survival Technology accurately classified the drug as an S drug because the drug had no FDA-approved therapeutic equivalents (nor has it ever had any therapeutic equivalents).

56. In 1996, Survival Technology merged with Brunswick Biomedical to form Meridian Medical Technologies Inc. ("Meridian"), and in 1997, Dey Inc. ("Dey"), a subsidiary of Merck KGaA ("Merck"), acquired the exclusive right to market and distribute the EpiPen from Meridian.[25]

D. Mylan Knowingly or Recklessly Misclassified the EpiPen for the Purposes of the MDRP Ever Since It Began Selling the EpiPen to Medicaid.

57. On October 2, 2007, Mylan acquired exclusive rights to market the EpiPen from Dey and Dey's parent company Merck, as part of its acquisition of Merck's generics business. Meridian retained ownership of the patents relating to the EpiPen. Mylan continued Dey's sales of EpiPen to Medicaid. From October 2, 2007 to the present, the responsibility of correctly classifying the EpiPen for the purposes of the MDRP shifted to Mylan.

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[24] Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator (Oct. 5, 2016) at 2.

[25] Meridian was acquired in January 2003 by King Pharmaceuticals, which was then acquired by Pfizer, Inc. ("Pfizer") in 2010; accordingly, Meridian is now a subsidiary of Pfizer. Pfizer, through Meridian, currently owns the non-expired patents on the EpiPen and currently manufactures the EpiPen for Mylan, while Mylan has exclusive rights to sell and market the EpiPen.

58. As the following facts make clear, from 2007 to the present, Mylan knowingly or recklessly misclassified the EpiPen as a generic N drug for the purposes of the MDRP.

1. Proper Classification of the EpiPen As a Brand Drug Is Straightforward Under Applicable Laws and Regulations

59. While Mylan is a massive multinational corporation valued at billions of dollars, and had an army of sophisticated lawyers available to provide advice in 2007 and thereafter on the proper classification of the EpiPen, the proper classification of the EpiPen required no sophisticated legal expertise at all.

60. Mylan's classification of the EpiPen as a generic N drug for the purposes of the MDRP was manifestly contrary to the 1990 Act and to the 2007 Regulations, both of which clearly required that all drugs that are approved under NDAs must be classified as S or I drugs. The question whether a drug was approved under an NDA is not a puzzle—if Mylan somehow did not gather from Dey the application type under which the EpiPen was approved, Mylan easily could have looked up the application type through the FDA, including through a simple online search.[26] As the EpiPen was approved under an NDA, the 1990 Act and the 2007 Regulations required Mylan to classify the EpiPen as an S or I drug.

61. While there was no ambiguity in this classification requirement, the 1990 Act and the 2007 Regulations also make clear that in no event may a drug that has no FDA-approved therapeutic equivalent be classified as an N drug. Again, whether a drug has an FDA-approved therapeutic equivalent is not a puzzle—under the 1990 Act as drug has a therapeutic equivalent if such an equivalent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." The text of the 2007 Regulations themselves included a

[26] The application type is appears at U.S. Food and Drug Administration, Drugs@FDA: FDA Approved Drug Products, *available at* http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430 (last visited March 20, 2017).

government website address drug manufacturers could visit to determine whether a drug had a therapeutic equivalent:

> For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at http://www.fda.gov/cder/orange/default.htm or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857;

62. The EpiPen has never had an FDA-approved therapeutic equivalent. In fact, in recent years Mylan filed a citizen's petition with the FDA in which it argued that the epinephrine autoinjector from a competitor, Teva Pharmaceutical Industries Ltd. ("Teva"), was not therapeutically equivalent to the EpiPen. Mylan argued that Teva's autoinjector lacked certain patented features of the EpiPen and required the user to remove two caps in order to use the device correctly, whereas the EpiPen required the user to remove only one cap before use. Mylan submitted data from studies that, according to Mylan, indicated that users accustomed to use of the EpiPen would not reliably use Teva's autoinjector correctly in an emergency due to these differences and others in the designs of the injectors. Mylan expressly argued that a difference in the design of an injector can create a therapeutic advantage for one product over another, even if the two products are both injectors of the same drug. The FDA ultimately determined that Teva's epinephrine autoinjector was not therapeutically equivalent to the EpiPen.

63. As the EpiPen has never had an FDA-approved therapeutic equivalent, the EpiPen cannot be classified as a generic N drug under the 1990 Act and the 2007 Regulations. For this additional reason, Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations.

2. Mylan and the Individual Defendants Repeatedly Affirmed in SEC Filings the Simple Rule that Drugs Approved Under an NDA Are Brand Drugs for the Purposes of the MDRP

64. Mylan and the Individual Defendants knew or recklessly disregarded that Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations. In Mylan's 10-K filings throughout the Class Period, Mylan admitted that:

> The required rebate [under the MDRP] is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs required manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

In these SEC filings, Mylan, and the Individual Defendants who signed them, made clear that they understood the MDRP to require drug companies to rebate products based entirely on whether those products were marketed under NDAs or under ANDAs. As the EpiPen was marketed under an NDA, Mylan's own SEC disclosures imply that Mylan was required to give Medicaid the greater rebate applicable to brand drugs (of approximately 23% of the average manufacturer's price) for the EpiPen.

3. CMS Expressly Informed Mylan Prior to the Start of the Class Period That Mylan's Classification of the EpiPen Was Incorrect

65. CMS expressly told Mylan that its classification of the EpiPen as a generic N drug was incorrect. On March 12, 2009, following the release of a report prepared by the HHS Inspector General ("HHS IG") titled "Accuracy of Drug Categorizations for Medicaid Rebates," CMS staff requested the HHS IG to provide it with a list of the eight drugs the HHS IG had determined to be incorrectly classified for the purposes of the MDRP in the course of its preparing the report. In response to this request, on March 16, 2009 the HHS IG provided CMS

with the list of misclassified drugs, and that list included the EpiPen. Subsequently, CMS notified Mylan about the misclassification. As CMS Acting Administrator Andrew M. Slavitt stated in a letter to Senator Ron Wyden, "The Center for Medicaid and CHIP Services in CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that [the EpiPen] is incorrectly classified."[27] As CMS itself was expressly informed by the HHS IG on March 16, 2009 that the EpiPen was misclassified for the purposes of the MDRP, on information and belief, CMS was not derelict in performing its duties and told Mylan that the EpiPen was misclassified for the purposes of the MDRP shortly after having that misclassification highlighted to it by the HHS IG, and well before the start of the Class Period.

4. Since 2004, Four New Patents Covering the EpiPen Have Been Granted, and Mylan Has Vigorously Participated in the Enforcement of Those Patents

66. Events in the years following Mylan's initial classification of the EpiPen as an N drug further demonstrate that its misclassification was knowing or, at a minimum, extremely reckless. Since 2004, Meridian Medical Technologies, Inc. ("Meridian") has received four additional patents for features that were subsequently integrated into the EpiPen: U.S. Patent Numbers 7,449,012, 7,794,432, 8,048,035, and 8,870,827 (the "EpiPen Patents"). These four patents have a priority date (*i.e.*, the date used to establish the novelty and/or obviousness of a particular invention relative to prior art) of August 6, 2004, and all will expire in 2025. These patents substantially altered the product Mylan acquired from Dey. As Mylan spokeswoman

[27] Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator (Oct. 5, 2016) at 2.

Lauren Kashtan has stated, "As anyone who has used the product knows, the epinephrine auto-injector we have in the market today is substantially different than the one we acquired."[28]

67. The issuance of the EpiPen Patents, and Mylan's designation of these patents as covering the EpiPen, further show that Mylan was acting disingenuously in classifying the EpiPen in effect as a generic rather than as a brand drug for the purposes of the MDRP. Mylan's disingenuousness is underscored by the fact that Mylan vigorously and repeatedly sought to enforce these patents by participating in multiple lawsuits challenging potential generic competitors to EpiPen.

68. In 2009, Meridian and Mylan filed a patent lawsuit ("2009 Lawsuit") against Teva, which was preparing to introduce an epinephrine auto-injector that would compete with EpiPen. The 2009 Lawsuit accused Teva of seeking to "manufacture and sell a generic version of . . . [the] highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent Nos. 7,449,012 B2 (the "'012 patent") and 7,794,432 B2 (the "'432 patent"), which expire on September 11, 2025.

69. The 2009 Lawsuit noted that Meridian was "the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3mg/0.3 mL and 0.15 mg/0.3 mL ('EpiPen® Autoinjector')." It also noted that Meridian had "submitted information concerning the '012 patent and '432 patent for listing in the FDA's [Orange Book] on July 17, 2009 and September 15, 2010, respectively." The 2009 Lawsuit further claimed that Teva's application to the FDA for its classification of its proposed product "constitute[d] an act of infringement" of the EpiPen Patents at issue.

[28] Intelligent Investments, *Mylan: $5 Billion Potential Liability from EpiPen Underpayment of CMS Rebates*, Seeking Alpha, at 6 (Feb. 6, 2017) (quoting statement made to NBC News).

70. A similar lawsuit was filed in 2010 against Sandoz, Inc. ("Sandoz") ("2010 Lawsuit"). The 2010 Lawsuit challenged the proposed "manufacture and s[ale] [of] a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector," and asserted the same patents as the 2009 Lawsuit. Like the 2009 Lawsuit, the 2010 Lawsuit asserted that Sandoz's application to the FDA for its proposed product "constitute[d] an act of infringement" of the EpiPen Patents at issue.

71. In 2011, yet again, Mylan, in concert with Meridian, asserted the EpiPen Patents, this time in a lawsuit ("2011 Lawsuit") against Intelliject, Inc. ("Intelliject"). Like Teva and Sandoz before it, Intelliject sought to introduce a competitor to EpiPen. Like the 2009 and 2010 Lawsuits, Mylan, in concert with Meridian and King, asserted the EpiPen patents to prevent Intelliject from proceeding in marketing its product, and argued that Intelliject's application to the FDA "constitute[d] an act of infringement" of the EpiPen Patents at issue.

5. In 2014, the DOJ Issued a Subpoena to Mylan Regarding Mylan's Misclassification of the EpiPen

72. In November 2014, Mylan received a subpoena from the DOJ as part of the DOJ's investigation into "whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."[29] Accordingly, by November 2014 at the very latest, the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan's classification of the EpiPen for the purposes of the MDRP was potentially incorrect.

[29] Mylan N. V., Quarterly Report (Form 10-Q) at 56-57, (Nov. 9, 2016).

6. Mylan Marketed the EpiPen as a Brand Name Drug

73. Mylan's classification of the EpiPen as a generic drug is also in obvious tension with Mylan's treatment of the EpiPen as a brand drug for all purposes other than the classification of this drug under the MDRP. After acquiring the right to the EpiPen, Mylan embarked on a years-long marketing campaign with the express purpose of promoting the EpiPen as an irreplaceable, unequalled, life-saving brand-name drug. That campaign has resulted in the EpiPen brand being compared to "Kleenex" amongst doctors, according to a 2015 Bloomberg article. Indeed, in August 2015, Bresch touted "the brand equity with EpiPen" as a reason not to worry about the prospect of impending generics.

74. Further, Mylan tacitly acknowledged that one of the reasons for the EpiPen's skyrocketing prices is that the EpiPen is a brand-name drug, and not a generic drug. Specifically, in December 2016, in the wake of controversy over EpiPen's rising prices, Mylan introduced an "authorized generic" to the EpiPen priced at $300, less than half the EpiPen's list price. Such a measure would not have been needed were the EpiPen truly a generic drug, as Mylan claimed it to be in classifying the EpiPen as a generic N drug for the purposes of the MDRP.

75. Mylan wanted to have it both ways—it wanted be able to charge the high prices commensurate with brand-name drugs, while reimbursing the government as little as possible under a classification intended to account for the lower profit margins associated with generic drugs. For years, Mylan succeeded in doing so.

E. Mylan Knowingly or Recklessly Misled Investors Concerning its Misclassification of the EpiPen

76. Throughout the Class Period, Mylan misled investors about its misclassification of the EpiPen. In its annual and quarterly filing with the SEC, Mylan repeatedly and

intentionally and/or recklessly led investors to believe that the classification of its drugs for the purposes of the MDRP was "complex and often involve[d] subjective decisions," and was subject to "risk of errors and differing interpretations." Moreover, Mylan repeatedly stated that there could be "ambiguity with regard to how to properly calculate . . . payments to Medicaid." These statements failed to disclose the true situation Mylan faced with respect to its classification of the EpiPen, namely that Mylan's classification of the EpiPen was blatantly incorrect under applicable law and regulations. The classification of the EpiPen was not complex and did not involve subjective decisions—as explained above, the classification was simple and straightforward and turned simply on whether the drug at issue had been approved under an NDA (a yes or no matter that can be determined by looking on a government website), and whether the drug had therapeutic equivalents (also a yes or no matter that can be determined by looking on a government website). And the classification was not subject to a "risk of error"—that risk of error had materialized, as Defendants knew or were reckless in not knowing that the EpiPen was incorrectly classified. Likewise, the classification was not subject to "differing interpretations"—looking on the FDA website to check whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise.

77. These and Defendants' numerous other misleading statements regarding its misclassification of the EpiPen are detailed in Part VII infra.

F. Mylan Knowingly Misled the Public by Implying Mylan Was Not Being Investigated for Its EpiPen Classification When in Fact It Was

78. Separately and independently, Mylan misled investors regarding whether a government authority had taken a position contrary to positions Mylan had taken regarding its classification of the EpiPen, and whether Mylan was being investigated for its EpiPen classification.

79. Throughout the Class Period in its quarterly and annual filings, Mylan stated that "should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken . . . ." These statements were misleading from the start of the Class Period because, as explained above, prior to the Class Period CMS had informed Mylan that its classification of the EpiPen was incorrect. Accordingly, there was not merely a possibility that a government agency might take a position contrary to Mylan's regarding its classification of the EpiPen—rather, a government agency had already taken a contrary position on that subject and had conveyed its contrary position to Mylan.

80. Moreover, on and after November 2014, Mylan's statements that a government agency "may take a position contrary to a position we have taken" became doubly misleading because as of that date, the DOJ already had commenced an investigation relating to Mylan's misclassification of the EpiPen. That is, by November 2014, the DOJ had indicated to Mylan that it had taken a position contrary to Mylan's with respect to Mylan's classification of the EpiPen, namely, that there was a substantial likelihood that Mylan had misclassified the EpiPen.

81. Mylan also misled investors concerning whether it was being investigated for its EpiPen classification. From the beginning of the Class Period, and in particular from November 2014 until November 2016, Mylan stated in its annual and quarterly SEC filings that "[a]ny failure to comply with [its payment obligations related to Mylan's participation in Medicaid] could subject us to investigation . . . ." In stating that Mylan was subject to a risk of investigation for a failure to comply with its Medicaid payment obligations, including a failure to comply with its obligation to classify the EpiPen correctly for the purposes of the MDRP, without also disclosing that that risk already had materialized when the DOJ commenced an

investigation into Mylan's classification of the EpiPen, Mylan misled investors to believe that no such investigation was underway when in fact it was.

82. These and Mylan's numerous other misleading statements regarding whether a governmental authority had taken a position contrary to its own regarding its classification of the EpiPen and regarding the existence of an investigation into Mylan's classification are detailed in Part VII infra.

G. Mylan's Misclassification of the EpiPen and the Significance of the Misclassification Were Revealed Starting in September 2016

83. Starting in September 2016, the truth about Mylan's misclassification of the EpiPen for the purposes of the MDRP, and the significance of that misclassification for Mylan's finances, was revealed to the market over a series of months. Some of these revelations are as follows.

1. A Bipartisan Group of U.S. Senators Requested that the DOJ Investigate Mylan's Classification of the EpiPen

84. In a September 2016 letter, Senators Richard Blumenthal (D-Conn), Senator Chuck Grassley (R-Iowa) and Senator Amy Klobuchar (D-Minn), called on Attorney General Loretta Lynch to investigate Mylan's classification of the EpiPen for the purposes of the MDRP. The letter noted that the EpiPen had not faced any FDA-approved competitors and that Mylan actively had prevented other drug marketers from introducing competing products; the letter concluded that the EpiPen was an "innovator drug" subject to the higher rebate under the MDRP. The letter stated that the facts "suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes."

2. Mylan Agreed To Pay a $465 Million Settlement with the DOJ over Its Misclassification of EpiPen

85. On October 7, 2016, Mylan announced in a press release that it had agreed to the terms of a $465 million settlement with the DOJ and other government agencies "that w[ould] resolve questions that ha[d] been raised about the classification of . . . EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program." The press release explained that "the question in the underlying matter was whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs." The press release further stated that the settlement terms would resolve claims over "whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula."

86. According to numerous press reports, the settlement terms also required Mylan to pay a higher rebate rate for EpiPen to Medicaid starting on April 1, 2017.

87. Following Mylan's press release, numerous members of Congress criticized the purported DOJ settlement with Mylan for being excessively lenient. For example, on October 21, 2016, Senator Elizabeth Warren called the announced settlement "shamefully weak" and "shockingly soft." According to Senator Warren, the announced settlement size was too small, and may have "rewarded" Mylan by allowing it to keep an additional $65 million that it had made by "defrauding Medicare and Medicaid." Senator Warren determined that Mylan has underpaid at least $530 in Medicaid rebates, and financial analysts have determined that

Mylan's underpayments were even greater.[30] Senator Richard Blumenthal of Connecticut similarly called on the Justice Department to reject the announced settlement.

88. To date, Mylan's announced settlement with the DOJ has not been finalized or confirmed by the DOJ.

3. The SEC Opened an Investigation into Mylan Regarding Its Classification of the EpiPen in October 2016

89. The same day Mylan announced its purported settlement with the DOJ, October 7, 2016, Mylan received "a document request from the Division of Enforcement at the SEC seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints."

90. Mylan did not disclose this SEC document request until a month later, in its Form 10-Q filed with the SEC on November 9, 2016.

V. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN ANTICOMPETITIVE CONDUCT TO ALLOW IT TO INFLATE THE PRICE OF THE EPIEPEN

91. Separate and apart from Mylan's overcharging Medicaid for over a decade for its purchases of the EpiPen, Mylan engaged in anticompetitive conduct during the Class Period in an attempt to prevent or delay competition against the EpiPen. In particular: (1) in settling its patent infringement suit against Teva Pharmaceuticals ("Teva") relating to the patents covering the EpiPen, Mylan, in concert with Meridian Medical Technologies ("Meridian") and King Pharmaceuticals ("King"), which are now part of Pfizer, agreed to give Teva an undisclosed "reverse payment" in exchange for Teva's agreeing to delay introducing its generic epinephrine autoinjector into the market until 2015, in a so-called "pay-for-delay" scheme; and (2) Mylan entered into exclusive dealing agreements with schools under which Mylan agreed to sell the

[30] According to Evercore ISI senior analyst Umer Raffat, Mylan may have shortchanged Medicaid $707 over the past five years.

EpiPen to these schools at a discount in exchange for an agreement by the schools not to purchase any product competitive with the EpiPen.

92. Mylan misled investors by failing to disclose this anticompetitive conduct and the risk this conduct created that federal agencies would investigate Mylan for such conduct. When this conduct was revealed and when the risk of investigation materialized, Mylan's stock dropped precipitously, injuring Plaintiffs and the Classes.

A. Mylan Failed To Disclose That It Paid Teva To Delay Introducing a Generic Epinephrine Autoinjector

93. In December 2008, Teva filed an ANDA with the FDA in which it sought approval for a generic epinephrine autoinjector. On July 20, 2009, Teva filed a certification with the FDA in which it stated that the four patents Mylan claimed covered the EpiPen were invalid or were not infringed by Teva's autoinjector. Patent holders who believe that a device filed under the certification infringes their patents may bring suit immediately for patent infringement upon the filing of the certification. Based on this right, on August 28, 2009, in concert with Mylan, Meridian and King, which own the four patents Mylan claims to cover the EpiPen, sued Teva in concert with Mylan for infringement of two of these patents, the '012 and '432 patents.

94. The parties submitted their constructions of the patent claims at issue to the Court in a *Markman* hearing. On October 17, 2011, the Court issued constructions that were favorable to Teva. On February 16 and March 7, 8 and 9, 2012, the Court held a bench trial, and on April 26, 2012, the parties entered into a settlement agreement resolving the patent litigation (the "2012 Settlement Agreement").

95. Mylan had knowledge of all material terms of the 2012 Settlement Agreement and acted in concert with Pfizer in reaching the 2012 Settlement Agreement. On the same date

that Meridian and Teva entered the 2012 Settlement Agreement, Mylan announced the settlement in a press release titled "Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement with Teva." That press release made clear that the terms of the 2012 Settlement Agreement provided that Teva would delay introducing its generic epinephrine autoinjector for over three years:

> According to the terms of the settlement, Teva may launch a generic epinephrine auto-injector covered by its ANDA on June 22, 2015 or earlier under certain circumstances, subject to receipt of approval from the U.S. Food and Drug Administration.
>
> [. . .]
>
> Additional terms of the agreement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

96. Mylan's active participation in the 2012 Settlement Agreement is wholly understandable: while Mylan was not formally a party to the lawsuit, Mylan's interests in the outcome of the litigation were as great or greater than those of Meridian and King.[31] Moreover, Mylan was the party who listed the patents at issue in the Orange Book as covering its product the EpiPen, and so was formally responsible for creating the legal conflict that the 2012 Settlement Agreement resolved.

97. While the terms of 2012 Settlement Agreement other than those announced by Mylan are confidential, according to an analysis by Rutgers Law School professor Michael A. Carrier, the 2012 Settlement Agreement likely contained a provision that required Mylan to give Teva a monetary payment as consideration for Teva's agreement to delay introducing its generic

[31] Indeed, after the settlement, Mylan filed a citizens petition with the FDA pursuant to 21 C.F.R. § 10.30 based on questionable studies in which Mylan claimed that Teva's epinephrine autoinjector was not therapeutically equivalent to the EpiPen, and this petition was timed in order to prolong maximally the FDA's potential approval of Teva's competing product.

epinephrine autoinjector into the market for over three years.[32] This provision, called a "reverse payment" or a "pay-for-delay" agreement, violates antitrust law where, as here, the monetary payment is offered as consideration primarily to achieve the anticompetitive effect of delaying the entry of a competitive drug into the market.

98. That the 2012 Settlement Agreement more likely than not contained an anticompetitive "pay-for-delay" provision reasonably may be inferred from a few publicly available facts. Although the complete terms of 2012 Settlement Agreement have not been released to the public, these terms have been released to the FTC. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, pharmaceutical companies must file patent infringement agreements with the FTC and the Department of Justice within ten days of their execution.

99. In January 2012, the FTC published a guide titled "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," in which the FTC detailed its positions with respect to pay-for-delay agreements. In that publication, the FTC stated that "[a]bsent compensation to the generic for the delay in its entry, [patent] settlement agreements are unlikely to raise antitrust issues." On January 30, 2017, Bloomberg reported that Mylan had received a request for information from the FTC regarding whether Mylan entered any agreements that delayed cheaper versions of the EpiPen from coming to the market. As the FTC, according to its stated position, believes that patent settlement agreements that do not provide "compensation to the generic for the delay in its entry" "are unlikely to raise antitrust issues," the FTC's investigating the EpiPen-related settlement agreement in which Mylan has

[32] Michael A. Carrier and Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 Cornell L. Rev. Online 53 (2017).

admitted involvement suggests that that settlement agreement did provide "compensation to the generic for the delay in its entry."

100. As a result of Mylan's anticompetitive conduct, Mylan was able to increase the price of the EpiPen by more than 400% between 2009 and 2016 to more than $600 for a two-pack. A typical dose of epinephrine itself costs only cents to manufacture. This enormous price increase forced countless families with members, including children, who suffer from severe allergies to pay dearly for this potentially life-saving drug or else risk the death of a loved one. Mylan repeatedly misled the investing public about this misconduct throughout the Class Period.

B. Mylan Required Schools To Agree Not To Purchase Products Competitive with the EpiPen in Order To Purchase EpiPens at an Affordable Price

101. Mylan's efforts to reduce competition against the EpiPen extended beyond in its efforts to prevent generic competitors from entering the market—Mylan also thwarted competition against the EpiPen by requiring schools to which it marketed the EpiPen during the Class Period to sign exclusive dealing agreements with Mylan. These schools included public and private schools serving children in kindergarten through high-school. Under the terms of these agreements, schools were required not to purchase products that competed with the EpiPen in order to receive a discount on their purchases of the EpiPen—the agreements required that schools "not in the next twelve (12) months purchase any products that are competitive to EpiPen® Auto-Injectors."[33] This language was contained in school contracts over a number of years, including at least 2014, 2015, and 2016.[34] In agreeing to this provision, schools were

[33] Ike Swetlitz & Ed Silverman, *Mylan May Have Violated Antitrust Law in its EpiPen Sales to Schools, Legal Experts Say*, Stat, Aug. 25, 2016.

[34] *Id*.

able to purchase the EpiPen at a price roughly equal to a quarter of the price charged to pharmacies.[35] The Terms of these exclusivity agreements were not disclosed to investors.

102. These agreements violated federal antitrust laws, including Section 3 of the Clayton Act, which prohibits anticompetitive exclusive-dealing arrangements, and Section 2 of the Sherman Act, which prohibits wielding monopoly power unreasonably to prevent competition. The market for school purchases of epinephrine autoinjectors is a market distinct from, albeit related to, the market for individual purchases of such autoinjectors. Mylan has monopoly power in both markets: the EpiPen accounts for over 90% of sales of epinephrine autoinjectors in both markets. Mylan's exclusive dealing agreements with schools foreclosed a substantial portion of the market for school purchases of epinephrine autoinjectors. These exclusive dealing agreements had additional attendant anticompetitive effects, as Mylan's distribution of these devices to schools helped Mylan to familiarize parents with the EpiPen brand and the particular method of using this drug, which encouraged parents to favor the EpiPen over other epinephrine autoinjectors when purchasing them for private use.

103. Mylan's exclusive dealing agreements with schools violated antitrust laws, or at a minimum raised serious antitrust concerns. In entering these agreements, Mylan created a significant risk of public outcry and calls for antitrust investigation upon revelation of the terms of these agreements, which had the effect of limiting school children's access to potentially lifesaving epinephrine autoinjectors.

[35] *Id.*

VI. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN MARKET ALLOCATION AND PRICE-FIXING OF GENERIC DRUGS

104. During the Class Period, Mylan participated in a third massive, and separate, series of frauds on investors—Mylan engaged in a wide-ranging scheme to allocate the market between itself and competitors for at least one generic drug, doxycycline, in order to maintain its price at a supracompetitive level, and Mylan engaged in a scheme to fix the prices of at least five other generic drugs, albuterol sulfate, benazepril, clomipramine, divalproex, and propranolol, by agreeing with competitors to raise the prices substantially and simultaneously. Mylan misled investors about the competition it faced, the validity of its sales, and the risks the company faced by failing to disclose that it was engaged in this anticompetitive conduct relating to these generic drugs.

A. Anticompetitive Activity by Generic Drug Manufacturers Led to Widespread Increases in the Cost of Generic Drugs During the Class Period

105. The prices for a large number of generic pharmaceutical drugs skyrocketed throughout the Class Period. Nearly 10% of generic drugs more than doubled in price between July 2013 and July 2014 alone, according to data from CMS. In the same time period, the price of more than 1,200 generic drugs increased by an average of 448%. A study by Fideres Partners LLP, released on December 22, 2016, identified 90 medicines the prices of which rose at least 250 percent between 2013 and 2016, and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. A January 2014 survey of 1,000 members of the National Community Pharmacists Association ("NCPA") found that more than 75% of the pharmacists surveyed reported higher prices on more than 25 generic drugs, with the prices sometimes spiking by 600% to 2,000% in some cases.

106. Mylan's CEO Heather Bresch informed investors about her inclination to raise prices right around the start of Mylan's recent price-fixing. These comments indicated that Bresch was focused on raising the prices of generic drugs, even though the market forces were pushing the prices of generic drugs down.

107. For example, in Mylan's October 25, 2012 conference call with investors, Defendant Bresch stated, "You've heard me quarter after quarter coming and saying we weren't going to chase the bottom, that there's been irrational behavior and that we would continue to hold steady and control what we can control."[36]

108. Likewise, in Mylan's May 2, 3013 earnings call, Defendant Bresch stated:

> I think that there was very whacked-out prices, dirt cheap, literally cheaper than dirt for some of those older products. And the bar needs to go. It needed to go up from a quality perspective, and it needs to go up and get rebalanced from a pricing perspective. So I think that we have certainly seen that. And I'm not—there's extremes on both ends. But I think, overall, the bar is going up. And so that stability and that tide will go with it. And so I see that staying, because I think people realized the detriment it did to this therapeutic category by having the dynamics in place that were.[37]

B. Pricing Decisions at Mylan Were Reviewed and Approved by Mylan's Top Executives, Including the Individual Defendants, Who Were Fully Aware of Mylan's Market Allocation and Price Fixing Activity

109. Defendants Coury and Bresch, by virtue of their responsibilities and activities as CEO of the Company, Defendants Sheehan and Parks, by virtue of their responsibilities and activities as CFO, and Defendant Campbell, by virtue of his responsibilities and activities as the Company's Chief Accounting Officer, were privy to, and participated in, Mylan's fraudulent

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[36] Seeking Alpha, Tr. of Third Quarter Mylan Earnings Call (Oct. 25, 2012), *available at* http://seekingalpha.com/article/951051-mylan-management-discusses-q3-2012-results-earnings-call-transcript?part=single.

[37] Seeking Alpha, Tr. of Second Quarter Mylan Earnings Call (May 2, 2013), *available at* http://seekingalpha.com/article/1397171-mylan-management-discusses-q1-2013-results-earnings-call-transcript?part=single.

conduct described in this Complaint, including the market allocation and price-fixing schemes described in this Part.

110. A confidential witness ("CW") has confirmed that Defendants Coury and Bresch, as successive CEOs, and Defendants Sheehan and Parks, as successive CFOs, each knew of and approved all material drug pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan's Morgantown, West Virginia facility, which was at the time the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. CW was responsible for cost accounting and overseeing plant manufacturing operations. CW also conducted cost analysis on certain products to assess the current market. In CW's role as Director of Costing, CW worked directly with Defendant Sheehan and Mylan President, Tony Mauro. CW also attended company-wide meetings that were led by Defendant Bresch and concerned company initiatives.

111. CW stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. "[Price] was always a topic." CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW, Defendants Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For example, "[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at." CW understood the "anthrax antibiotic" in question to be doxycycline.

C. Mylan Conspired with Other Drug Companies To Allocate the Market for Doxy DR To Maintain Its Price at a Supracompetitive Level

112. When entering a generic drug market, Mylan and other generic drug companies routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.

113. On December 14, 2016, the attorneys general of twenty states (the "States") filed a joint complaint against Mylan that was the product of a years-long investigation.[38] In the complaint, the States detail the fruits of their investigation and tell the story, with great detail, of how Mylan agreed to allocate the market for Doxy DR with its competitors in order to maintain and increase the price of this drug at and to artificially high levels. The allegations in this subsection are based in whole or in part on that complaint.

114. Prior to 2013, Mylan was the only manufacturer of the generic drug Doxycycline Hyclate Delayed Release ("Doxy DR"). In 2013, Heritage Pharmaceuticals Inc. ("Heritage") became interested in selling Doxy DR as well. In mid-2013, Heritage executives began to reach out to Mylan executives in an effort to divide the market in order to refrain from competing with each other on prices.

115. On May 2, 2013, Jason Malek, Vice President of Commercial Operations at Heritage, requested that another Heritage employee set up a call between Malek and the Vice

[38] *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056, Complaint (Dkt. No. 1), at ¶ 55 (D. Conn. Dec. 14, 2016). On March 1, 2017, Connecticut filed an Amended Complaint that increased the number of states involved in the litigation from 20 to 40. The multistate group of plaintiff states now includes: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wisconsin.

President of Sales at Mylan, but that Heritage employee replied that the Vice President of Sales at Mylan had little to do with National Accounts and recommended that Malek contact another individual at Mylan. Malek promptly connected with the Mylan employee through the website LinkedIn. Over the next several weeks, Malek and the Mylan employee communicated by phone on multiple occasions.

116. Mylan and Heritage executives quickly became involved in the price fixing scheme. On May 7, 2013, Heritage's President and CEO, Jeffrey Glazer, emailed an executive at Mylan in an effort to discuss dividing the market for doxycycline. The Mylan executive responded with a phone number where he could be reached in England. The Mylan executive and Glazer spoke the next day.

117. During the course of these communications, Heritage and Mylan executives agreed to allocate the market for Doxy DR between Heritage and Mylan, and agreed further that the two companies would refrain from competing against one another for customers in that market. The objective of this agreement was to avoid a price war that would reduce profitability for both companies.

118. In these communications, Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business from that wholesaler to increase Heritage's market share.

119. On July 2, 2013, Heritage entered the market for Doxy DR. On the rare occasion during the course of its dealings with Heritage that Mylan insisted on competing for business to which Heritage believed it was entitled, Heritage contacted Mylan directly to address the situation, as occurred in a November 25, 2013 email between Malek at Heritage and a contact at Mylan. Malek emailed Glazer the same day, and Glazer's response confirmed that the purpose

of Heritage's agreement with Mylan was to maintain high prices in the market for Doxy DR. Glazer questioned whether Heritage should take any action that might disrupt that agreement.

120. In February 2014, Mayne Pharma (USA), Inc. ("Mayne") also entered the market for Doxy DR. Mayne approached Heritage even before it began selling the generic drug, in an attempt to obtain some of Heritage's market share. For example, on January 7, 2014, an employee at Mayne, spoke by phone with an employee at Heritage regarding obtaining some of Heritage's market share.

121. Shortly thereafter, Mayne made an unsolicited bid for the Doxy DR business of a large drug wholesaler. The bid prompted the wholesaler to approach Mylan, its supplier at the time of Doxy DR, to see whether Mylan would match Mayne's bid. At the same time, the wholesaler reached out to Heritage to see whether Heritage would also submit a bid for the wholesaler's Doxy DR business.

122. Internally at Heritage, Malek noted that Heritage had sufficient supply of Doxy DR to meet the requirements of the wholesaler and to place a bid for those requirements, but Malek and others at Heritage worried that Mylan would perceive such a bid as an attack on Mylan's Doxy DR business in violation of the market allocation agreement between Heritage and Mylan, a violation that could result in Mylan's retaliating against Heritage. Accordingly, the day after these internal discussions at Heritage took place, Heritage responded to the wholesaler that it declined to place a bid for the wholesaler's Doxy DR business. The reason Heritage gave to the customer to explain why Heritage could not submit a bid was that Heritage might not have enough supply to fulfill a contract with the wholesaler. Heritage's explanation, however, was a lie, because three days later, Heritage approached a different customer—a pharmacy chain—and asked if Heritage could bid for that company's Doxy DR business.

123. In late March 2014, Heritage learned that Mayne had made an unsolicited bid for Doxy DR to one of Heritage's large nationwide pharmacy accounts. On March 31, 2014, Malek emailed Mayne, and over the following day and weeks, Mayne and Heritage communicated extensively via text message and email regarding Mayne's unsolicited bid. These communications were conveyed to Heritage CEO Jeff Glazer in early April 2014. This conflict was resolved when Mayne agreed to walk away from the large account.

124. In November 2014, Mayne made offers to the One Stop Program of McKesson Corporation ("McKesson"), a drug wholesaler, and Econdisc Contracting Solutions ("Econdisc"), a group purchasing organization that includes Express Scripts, Kroger and Supervalu. Malek contacted personnel at Mayne to discuss the situation and raised the idea that Heritage and Mayne could allocate customers by having Mayne withdraw its offer to McKesson. Malek worked out an agreement with Mayne by November 25, 2014, which Glazer subsequently confirmed. Follow up communications occurred in December 2014 by text messaging and an in-person meeting at a conference of the American Society of Health-System Pharmacists held on December 9, 2014.

125. The agreement resulted in elimination of price competition and higher prices for doxycycline. When Econdisc put its business out for bid again in January 2015, Heritage deliberately bid a higher price than Mayne, fulfilling its agreement to walk away from the Econdisc business. Likewise, when Heritage was requested to submit a bid by a large nationwide pharmacy chain in September 2015, it declined to do so after learning Mayne was the incumbent supplier.

126. Mylan and Heritage also continued to honor their agreement to allocate market share of Doxy DR and to avoid competing against each other. For example, on August 29, 2014, Malek emailed a contact at Mylan and indicated that their agreement was still in effect.

D. Mylan Entered a Price Fixing Agreements with Competitors To Fix the Price of Certain Generic Drugs, Including Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol

127. During the Class Period, Mylan entered into and maintained price-fixing agreements with the other major participants in the markets for the generic drugs albuterol sulfate, benazepril, clomipramine, divalproex, and propranolol (the "Price-Fixed Drugs") that covered all of its generic Price-Fixed Drug products.

1. Albuterol Sulfate

128. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for albuterol sulfate, a bronchodilator used to treat asthma and other respiratory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

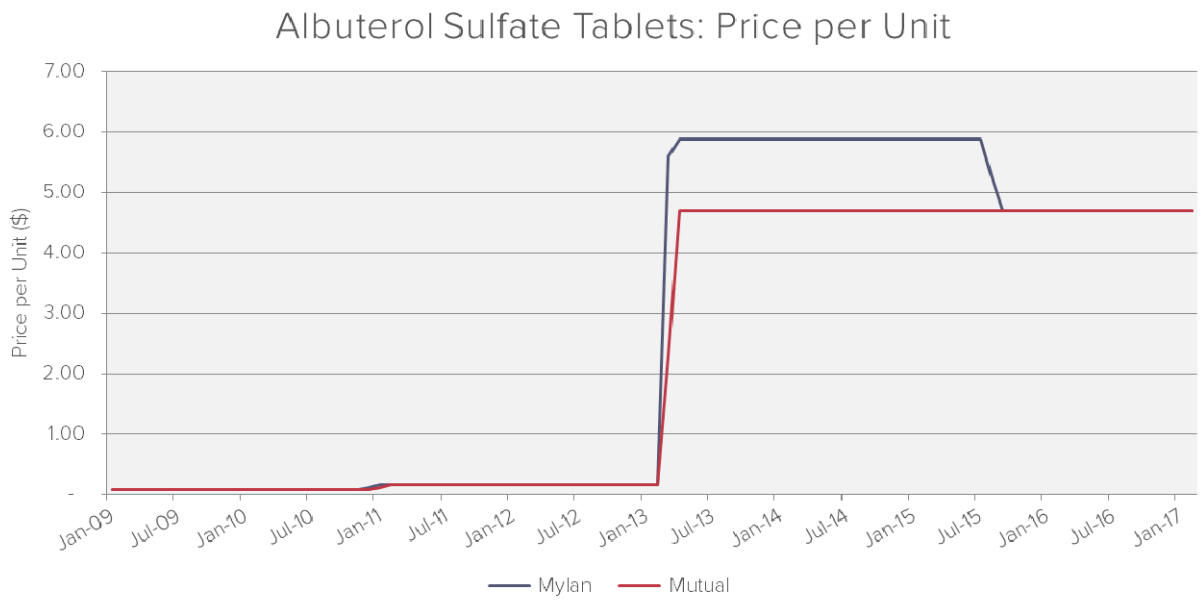
129. As shown below in Figure A, during the Class Period, the price at which Mylan sold albuterol sulfate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug.[39] Figure A shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of albuterol sulfate.

[39] Figures A-E are based Wholesale Acquisition Cost ("WAC") data obtained from Symphony Health Solutions. Each colored line in Figures A-E represents the weighted average price the associated drug marketer charged over time for each unit of the specified drug, averaged across all product strengths sold by the drug marketer for the indicated form of that drug. If a drug marketer held less than 1% of the market for a Fixed-Price Drug, the pricing of that drug marketer was excluded from calculations for the period during which its market share was less than 1%.

130. Before 2013, pricing for albuterol sulfate had for years remained stable, as is typical in a mature market. However, as shown in Figure A, the price of albuterol sulfate charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of albuterol sulfate including on February 20-22, 2013 in Orlando, Florida, among other meetings.

131. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure A: Albuterol Sulfate



132. The magnitude by which Mylan and other marketers of albuterol sulfate increased the price of this drug is likewise telling. The average price of common dosages of albuterol sulfate, as measured by National Drug Acquisition Cost ("NADAC") data, increased by between 2870% and 4266% during the Class Period, and the average price of common

dosages of the drug increased by between 2653% and 3911% in a matter of days at some point during the Class Period.[40]

133. Table A below displays percentage increases in NADAC data for common dosages of albuterol sulfate. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on albuterol sulfate—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table A: Albuterol Sulfate

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Albuterol Sulfate 2 MG Tab	2013-05-16	**3911%**	February 2013	December 2015	**4266%**
Albuterol Sulfate 4 MG Tab	2013-05-23	**2653%**	March 2013	May 2013	**2870%**

2. Benazepril

134. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for benazepril, an oral medication used to treat high blood pressure. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

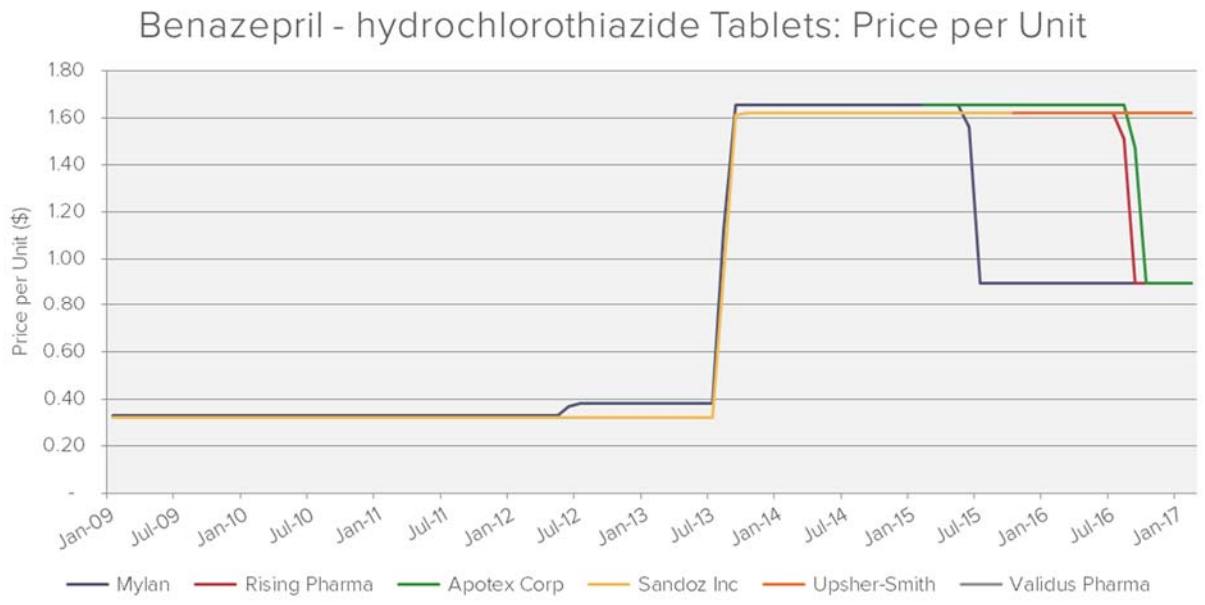
[40] NADAC ("National Average Drug Acquisition Cost") is based on CMS's monthly surveys of retail pharmacies to determine average acquisition cost for covered outpatient drugs.

135. As shown below in Figure B, during the Class Period, the price at which Mylan sold benazepril skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure B shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of benazepril.

136. Before 2013, pricing for benazepril had for years remained stable, as is typical in a mature market. However, as shown in Figure B, the price of benazepril charged by all major marketers of this drug, including Mylan, increased dramatically in the months following June 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of benazepril, including on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

137. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure B: Benazepril



138. The magnitude by which Mylan and other marketers of benazepril increased the price of this drug is likewise telling. The average price of common dosages of benazepril, as measured by NADAC data, increased by between 331% and 402% during the Class Period, and the average price of common dosages of the drug increased by between 263% and 368% in a matter of days at some point during the Class Period.

139. Table B below displays percentage increases in NADAC data for common dosages of benazepril. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on benazepril—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table B: Benazepril

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Benazepril-Hydrochlorothiazide 10-12.5 MG Tab	2013-11-21	**267%**	April 2013	November 2014	**377%**
Benazepril-Hydrochlorothiazide 20-12.5 MG Tab	2013-10-17	**263%**	March 2013	February 2014	**331%**
Benazepril-Hydrochlorothiazide 20-25 MG Tab	2013-11-07	**263%**	October 2013	July 2015	**347%**
Benazepril-Hydrochlorothiazide 5-6.25 MG Tab	2014-01-22	**368%**	December 2013	October 2014	**402%**

3. Clomipramine

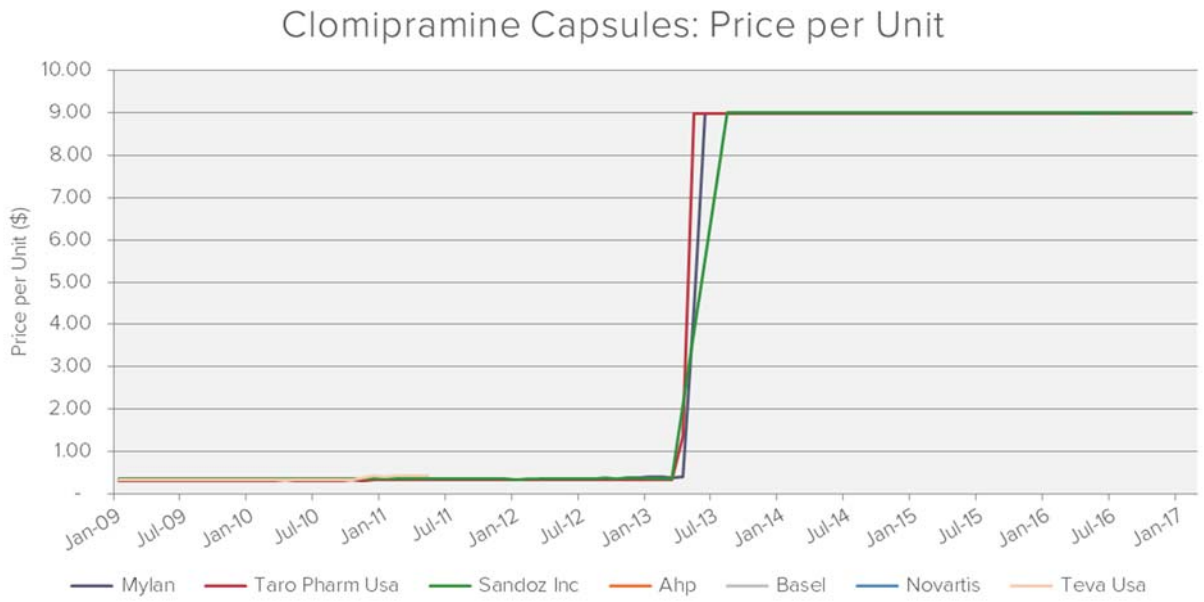
140. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

141. As shown below in Figure C, during the Class Period, the price at which Mylan sold clomipramine skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure C shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of clomipramine.

142. Before 2013, pricing for clomipramine had for years remained stable, as is typical in a mature market. However, as shown in Figure C, the price of clomipramine charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of clomipramine, including on February 20-22, 2013 in Orlando, Florida, among other meetings.

143. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure C: Clomipramine



144. The magnitude by which Mylan and other marketers of clomipramine increased the price of this drug is likewise telling. The average price of common dosages of clomipramine, as measured by NADAC data, increased by between 1973% and 3520% during the Class Period, and the average price of common dosages of clomipramine increased by between 1937% and 3482% in a matter of days at some point during the Class Period.

145. Table C below displays percentage increases in NADAC data for common dosages of clomipramine. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on clomipramine—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table C: Clomipramine

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Clomipramine 25 MG Capsule	2013-06-13	**3482%**	April 2013	March 2016	**3520%**
Clomipramine 50 MG Capsule	2013-06-13	**2640%**	March 2013	June 2013	**2701%**
Clomipramine 75 MG Capsule	2013-07-11	**1937%**	February 2013	November 2013	**1973%**

4. Divalproex

146. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for divalproex, used to treat certain types of seizures and migraines. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

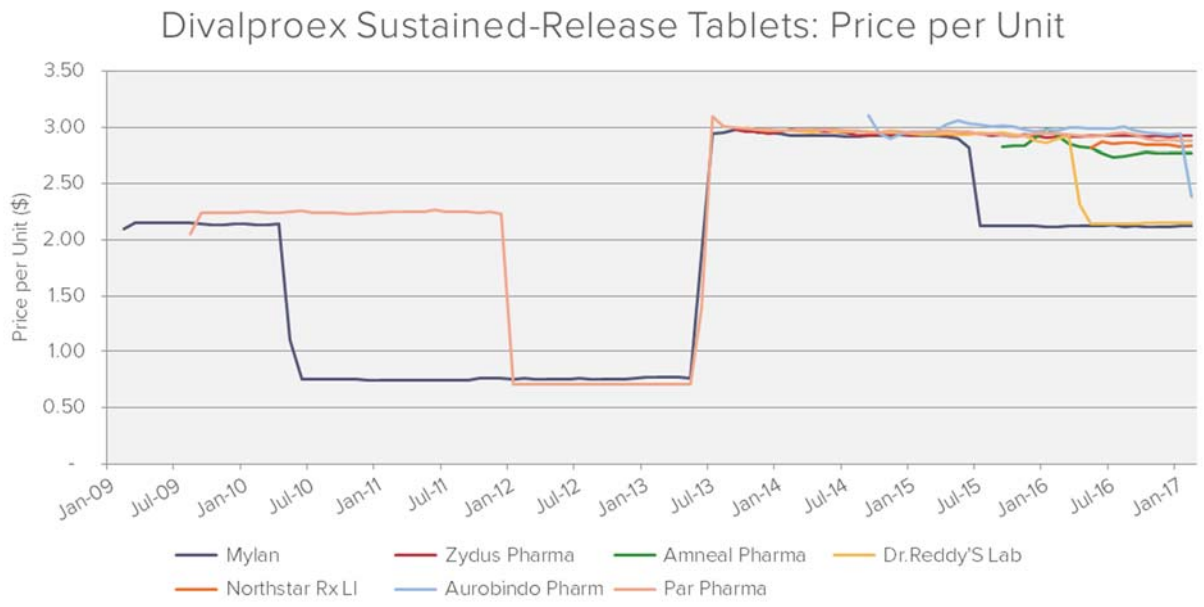
147. As shown below in Figure D, during the Class Period, the price at which Mylan sold divalproex skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure D shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of divalproex.

148. Before 2013, pricing for divalproex had for years remained stable, as is typical in a mature market. However, as shown in Figure D, the price of divalproex charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of divalproex, including

on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

149. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure D: Divalproex



150. The magnitude by which Mylan and other marketers of divalproex increased the price of this drug is likewise telling. The average price of common dosages divalproex, as measured by NADAC data, increased by between 685% and 1098% during the Class Period, and the average price of common dosages of divalproex increased by between 561% and 935% in a matter of days at some point during the Class Period.

151. Table D below displays percentage increases in NADAC data for common dosages of divalproex. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices

in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on divalproex—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table D: Divalproex

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Divalproex Sod ER 250 MG Tab	2013-09-19	**561%**	March 2013	September 2013	**685%**
Divalproex Sod ER 500 MG Tab	2013-09-19	**935%**	June 2013	September 2013	**1098%**

5. Propranolol

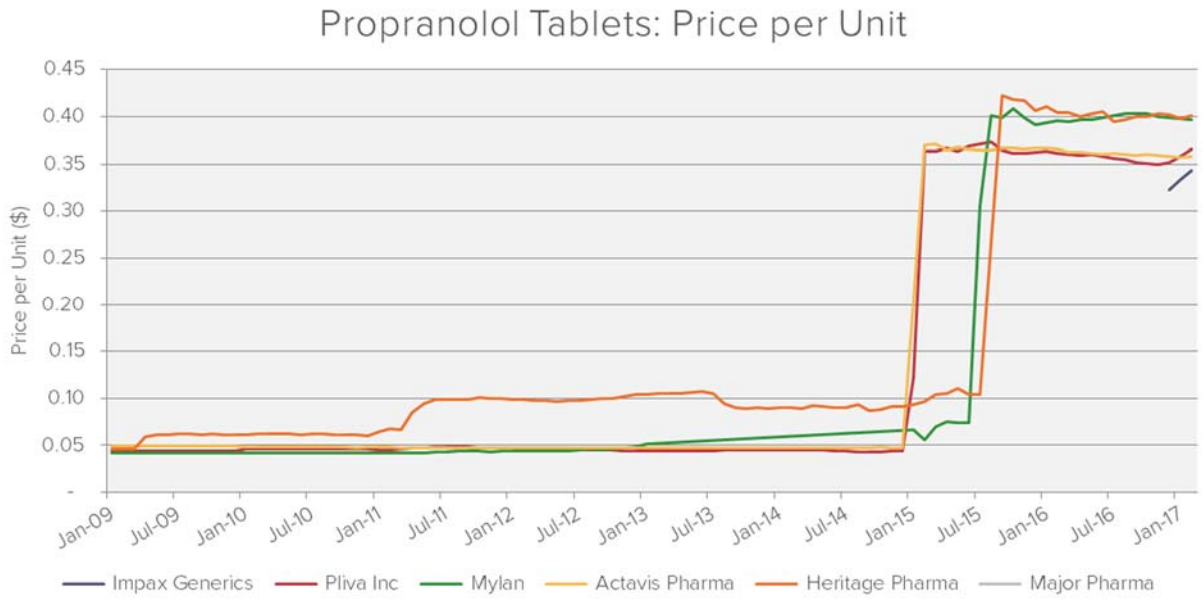
152. In or around beginning of 2015 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for propranolol, a beta-blocker used to treat and prevent heart attack and other heart and circulatory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

153. As shown below in Figure E, during the Class Period, the price at which Mylan sold propranolol skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure E shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of propranolol.

154. Before 2015, pricing for propranolol had for years remained stable, as is typical in a mature market. However, as shown in Figure E, the price of propranolol charged by all major marketers of this drug, including Mylan, increased dramatically in spring and fall of 2015

155. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure E: Propranolol



156. The magnitude by which Mylan and other marketers of propranolol increased the price of this drug is likewise telling. The average price of common dosages propranolol, as measured by NADAC data, increased by between 832% and 1124% during the Class Period, and the average price of common dosages of propranolol increased by between 39% and 356% in a matter of days at some point during the Class Period.

157. Table E below displays percentage increases in NADAC data for common dosages of propranolol. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes

clear that the drug cartel's price hikes on propranolol—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table E: Propranolol

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Propranolol 10 MG Tablet	2015-03-18	**210%**	December 2014	September 2015	**832%**
Propranolol 20 MG Tablet	2015-03-18	**330%**	October 2014	November 2015	**1047%**
Propranolol 40 MG Tablet	2015-03-18	**356%**	October 2014	February 2016	**1124%**
Propranolol 60 MG Tablet	2016-03-23	**39%**	November 2014	August 2015	**111%**
Propranolol 80 MG Tablet	2015-03-18	**295%**	October 2014	November 2015	**1113%**

158. The sudden, dramatic price increases of the prices for the Price-Fixed Drugs during the Class Period cannot be explained by benign market forces. During the Class Period, there were no significant increases in the cost of making, no significant decrease in the supply of, and no significant increases in demand for, the Price-Fixed Drugs. Federal law requires drug manufactures to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage. No supply disruptions were reported to the FDA during the Class Period that would explain the price increases. There were no similar price increases in other countries selling these generic drugs.

159. Accordingly, the only plausible explanation for Mylan's raising the prices of the Price-Fixed Drugs suddenly and stratospherically during the Class Period is that Mylan was acting in collusion with other generic drug manufacturers to fix the prices for these drugs.

160. These astronomical price increases caused, and continue to cause, significant harm to ordinary consumers, who rely on the Price-Fixed Drugs for their continued well-being.

Generic drugs are a critical part of the healthcare system in the United States, comprising nearly 8 in 10 prescriptions filled. A member survey by the National Community Pharmacists Association ("NCPA") found that the massive increases in the prices of generic drugs "are hurting patients and pharmacies' ability to operate" and that in some cases, "patients are declining their medication due to increased co-pays . . . ."[41]

E. Mylan's price increases on generic drugs would have been against its self-interest in the absence of price collusion.

161. Mylan's price increases on the Price-Fixed Drugs would have been against its self-interest in the absence of price collusion. Generic drugs, including the Price-Fixed Drugs, are a commodity, with any generic drug substitutable with another, and differentiated competitively with each other primarily based on price. In a market free of collusion, if one generic drug marketer raises its prices significantly above those of its competitors, that marketer will lose market share. Yet as explained above, Mylan and other drug marketers increased the prices of numerous generic drugs substantially during the Class Period.

F. The Structure of the Generic Drug Market Facilitated Mylan's Collusion

162. From at least 2013 to the present, the market structure for the Price-Fixed Drugs was highly conducive to the formation and maintenance of a price-fixing conspiracy. Publicly available data on the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol in the United States demonstrate that each is susceptible to cartelization by Mylan and other generic drug marketers. Factors that make the markets for the Price-Fixed Drugs highly susceptible to collusion include: (1) a high degree of industry concentration; (2) high barriers to entry; (3) demand inelasticity; (4) the lack of available substitutes; (5) a

[41] National Community *Pharmacists Association, Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-phramacists-say

high degree of interchangeability between the goods of cartel participants; (6) ease of, and opportunities for intercompetitor contacts and communication; (7) sufficient numbers to drive competition; (8) absence of departures from the market; (9) absence of non-conspiring competitors; (10) size of price increases; and (11) reimbursement of generic drugs.

1. High Degree of Industry Concentration

163. The markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are highly concentrated and each is dominated by a handful of companies.

164. The commonly accepted measure of market concentration is the Herfindahl-Hirschman Index ("HHI"). The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of three firms with shares of 20%, 30%, and 50%, the HHI is 3,800. Federal antitrust enforcement agencies consider markets in which the HHI is above 2,500 to be highly concentrated. In merger reviews, for instance, a proposed merger that would lead to a highly concentrated market, and an increase in the HHI of more than 200 points, creates a presumption of market power and a recognized risk of collusion. Throughout the relevant period, the HHI for some or all of the Price-Fixed Drugs was at a level that antitrust enforcement agencies consider indicative of a highly concentrated market vulnerable to collusion.

165. Concentration facilitates collusion because it reduces the number of negotiating partners and increases per-firm collusive profits. Concentration also significantly increases the stability of a cartel. One of the primary difficulties cartels face is cheating: each member has an individual incentive to lower prices slightly below the cartel price to capture significant market share. In a concentrated market, cheating is more easily prevented because each member of the cartel may more easily monitor the others and enforce compliance. In addition,

as the number of firms in a market decreases, the probability decreases that firms have different costs and differentiated products, which facilitates cartel formation and maintenance.

2. High Barriers to Entry

166. The presence of significant barriers to entry facilitates the operation of a cartel. Barriers to entry increase a market's susceptibility to a coordinated effort to maintain supracompetitive prices because it is difficult for new suppliers to enter the market and destabilize coordinated supracompetitive prices.

167. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol. As the dominant players in this market, Defendants were able to fix, raise, and maintain Mylan's prices for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol without competitive threats from rival generic drug manufacturers.

3. Demand Inelasticity

168. Price elasticity of demand is defined as the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. It is a measure of how demand for a product reacts to a change in price. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

169. For a cartel to profit from raising prices above competitive levels, demand for the product must be relatively inelastic such that any loss in sales will be more than offset by increases in revenue on those sales that are made. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to

buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

170. Generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol products are critical to the health of patients; they are considered medical necessities that must be purchased at whatever cost the Defendants offer them for sale. Thus, generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol products are excellent candidates for cartelization, because price increases will result in more revenue, rather than less.

171. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are necessary treatment for millions of patients for which no substitutes are available. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are thus particularly susceptible to collusive price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.

4. Lack of Available Substitutes

172. Many patients are unable to substitute other medications for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol. In some cases, Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are the only effective treatment for their conditions.

5. High Degree of Interchangeability of Generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol Products

173. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the

suppliers to agree on prices for the good in question and it is easier to monitor these prices effectively.

174. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are commodity products. Therefore, the products are interchangeable, as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, each drug manufacturer had to raise prices for the cartel to succeed. Indeed, as explained above, Mylan's raising its prices for the Price-Fixed Drugs was against its individual economic interest because its supposed competitors could have priced below Mylan's price and won substantial market share.

6. Ease of Information Sharing and Opportunities for Contact and Communications Among Competitors.

175. Mylan and other participants in the cartel communicated their present and future pricing decisions to each other, including in public settings such as earnings calls. By design, Mylan knew what the other cartel participants charged for their generic products, and what each was going to charge in the future. Price transparency and communications ensured that Mylan and other cartel members could monitor compliance with the cartel, and provided a mechanism by which each could assure the others that they would keep up their end of the bargain.

176. Mylan and other cartel participants are members of the same trade association: the Generic Pharmaceutical Association ("GPhA"). Senior executives of Mylan participate actively in the GPhA. For instance, Defendant Bresch currently chairs GPhA's board of directors. Representatives of Mylan and other cartel members met in person at GPhA meetings before and during the Class Period, including immediately before certain price increases for the

Price-Fixed Drugs were announced. The following table shows GPhA meetings at which Mylan was in attendance, and the dates and locations of these meetings.

Meeting	Meeting Date & Location
2012 GPhA Annual Meeting	February 22-24, 2012 Orlando, Florida
2012 GPhA Fall Technical Conference	October 1-3, 2012 Bethesda, Maryland
2013 GPhA Annual Meeting	February 20-22, 2013 Bethesda, Maryland
2013 GPhA CMC Workshop	June 4-5, 2013 Bethesda, Maryland
2013 GPhA Fall Technical Conference	October 28-30, 2013 Bethesda, Maryland
2014 GPhA Annual Meeting	February 19-21, 2014 Orlando, Florida

177. These in-person meetings provided additional opportunities to collude. As forty state attorneys general (the "States") have alleged: these trade shows "provide generic drug manufacturers . . . with ample opportunity to meet, discuss, devise, and implement a host of anticompetitive schemes that unreasonably restrain competition[.]"

178. Mylan and other generic drug companies use other industry trade shows and customer conferences to collude, including conferences hosted by the National Association of Chain Drug Stores, Healthcare Distributions Management Association (now known as the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing, among others. The States have alleged further:

> At these various conferences and trade shows, sales representatives from many generic drug manufacturers . . . have opportunities to interact with each other and discuss their respective business and customers. Attendant with many of these conferences and trade shows are organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors outside of the traditional business setting. Of particular importance here, generic drug manufacturer representatives who attend these functions, . . . use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and

pricing terms in their contracts with customers, among other competitively-sensitive information.

179. The States also have alleged that sales representatives of generic drug manufacturers "get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business." "In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as 'industry dinners.'" "At these industry dinners, one company is usually responsible for paying the dinner for all of the attendees. The company that pays the bill is generally determined by alphabetical order."

7. Sufficient Numbers to Drive Competition

180. While the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near direct cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would remain at competitive levels

8. Absence of Departures from the Market

181. There were no departures from the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol that could explain the price increases.

9. Absence of Non-Conspiring Competitors

182. Defendants have maintained supracompetitive pricing for generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic Albuterol Sulfate, Benazepril,

Clomipramine, Divalproex, and Propranolol markets, enabling price increases without loss of market share to non-conspirators. Indeed, no competitors not part of the conspiracy have emerged to undercut the Defendants' supracompetitive pricing.

10. Size of Price Increases

183. The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps—the increases are, in just one act, more than 200 times the current price of the product. A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.

11. Reimbursement of Generic Drugs

184. This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices is embedded in the generic reimbursement system. In the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales. However, when one observes significant price increases—particularly those of the kind alleged here—basic market economics dictates that the generic drug makers likely add an expectation that they would not lose volume (based on their expectations of what their ostensible competitors would do), because they colluded.

G. Mylan Misled Investors About the Competition it Faced and Validity of its Sales

185. Mylan repeatedly stated that the generic drug market is highly competitive. Mylan's statements about the highly competitive nature of the generic drug market were misleading to the extent that Mylan failed to state that the market for certain generic drugs had been allocated between competitors, and that the prices for certain drugs had been fixed at supracompetitive levels.

186. Mylan also made numerous statements regarding its sales of drugs and its related financial performance. Mylan's statements about its sales were misleading to the extent these figures were based on fixed prices, rather than prices dictated by market forces—investors believed these figures to be based on Mylan's performance in competitive markets, when in fact they were not.

187. These and Mylan's numerous other misleading statements relating to Mylan's market allocation and price-fixing activity are detailed in Part VII infra.

H. The DOJ, SEC, Congress and the States Have Responded to the Massive Increases in the Prices of Generic Drug Prices, Including the Price-Fixed Drugs

188. Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by the United States Congress and by federal and state antitrust regulators.

189. In a January 8, 2014 letter to members of key committees of the United States House of Representatives and Senate, Douglas P. Hoey, Chief Executive Officer of the National Community Pharmacists' Association, asked Congress to conduct an investigation of generic drug price increases.

190. In July 2014, the attorneys general of twenty states, including the Attorney General of Connecticut, began a wide ranging investigation into the pricing of generic drugs by generic drug companies, including Mylan.

191. On October 2, 2014, Representative Elijah E. Cummings ("Cummings"), Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernie Sanders ("Sanders"), Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, sent letters to drug manufacturers, including Mylan, asking for detailed information on the generic price hikes.

192. On November 20, 2014, Senator Bernie Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing in Price?" Various witnesses discussed the price hikes for generic drugs.

193. By November 2014, the DOJ commenced a wide-ranging criminal investigation of generic drug pricing and has caused grand jury subpoenas to be issued to various generic drug manufacturers, including Mylan, in connection with this investigation.

194. On February 24, 2015, Sanders and Cummings wrote a letter to the Office of the Inspector General ("OIG") of HHS, asking it to investigate the effects that price increases of generic drugs have had on generic drug spending within the Medicare and Medicaid programs. The OIG responded in a letter dated April 13, 2015, saying it planned to engage in a review of quarterly average manufacturer prices for the 200 top generic drugs from 2005 through 2014.

195. In December 2015, the DOJ issued Mylan and certain of its employees and senior management a subpoena relating to the marketing of some of Mylan's generic products, as well as "any communications with competitors about such products." Related search

warrants also were executed in connection with the DOJ's investigation. The DOJ probes initially were focused on two generic drugs: digoxin and doxycycline. Recent news reports have confirmed the DOJ's investigation is significantly broader and encompasses as many as a dozen generic drug manufacturers and is examining a conspiracy to fix, raise, maintain and stabilize the prices of as many as two dozen generic drugs, including the Price Fixed Drugs. (Moreover, these reports suggest that a leniency applicant came forward during the summer of 2016 and is working with the DOJ in its ongoing investigation.)

196. The DOJ investigation could result in the imposition of substantial fines and criminal pleas for Mylan, and jail time for Mylan executives. Some analysts have estimated that Mylan could face liability between $380 million and $770 million in fines and that the DOJ could impose industry-wide fines in excess of $1 billion.[42]

197. Also in December 2015, Mylan received a subpoena from the Attorney General of Connecticut regarding the price and marketing of Doxycycline.

198. On December 14, 2016, the attorneys general of twenty states, including the Attorney General of Connecticut, filed a civil case against six generic drug manufacturers, including Defendant Mylan. The States allege that their investigation, which is still ongoing, "uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States." The States' "initial civil action" concerned two generic drugs: Doxycycline Hyclate Delayed Release and Glyburide. The States have made clear that the evidence of wrongdoing they have uncovered extends far beyond the defendants and drugs identified in their "initial civil action." The Attorney General of Connecticut, George C. Jepson, whose office led the States' antitrust

[42] Eric Sandowsky, *DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says*, FiercePharma (Nov. 10, 2016), *available at* http://www.fiercepharma.com/pharma/doj-s-price-fixinginvestigation-could-lead-to-sizable-liabilities-analyst-says.

investigation, told the New York Times: "We believe that this is just the tip of the iceberg. I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit."

199. Also on December 14, 2016, the DOJ brought felony charges against two former senior generic pharmaceutical executives for their roles in conspiracies to fix prices, rig bids, and allocate customers for certain generic drugs. The DOJ alleged that Jeffrey Glazer, the former CEO of Heritage Pharmaceuticals, and Jason Malek, the former president of the same company, conspired to fix prices, rig bids, and allocate customers for doxycycline hyclate, an antibiotic. The DOJ also alleged that Glazer and Malek conspired to fix prices and allocate customers for glyburide, a medicine used to treat diabetes. This conspiracy included Mylan executives. The DOJ alleged that the "doxycycline hyclate conspiracy" began in approximately April 2013 and continued until at least December 2015.

200. On January 9, 2017, Glazer and Malek pled guilty to felony charges that they conspired with competitors to manipulate prices and allocate customers for doxycycline. Defendant Glazer admitted *that*:

> [He] participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products including Doxycycline Hyclate, the primary purpose of which was to allocate customers, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy. Defendant and his co-conspirators, including individuals that the defendant supervised at his company and those he reported to at his company's parent, engaged in discussions and attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States.[43]

[43] Tr. of Plea Hearing at 19:16-20:4, *United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id*. at 22:4-11 (admitting facts).

Defendant Malek admitted substantially the same facts.[44]

VII. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. Defendants' False and Misleading Statements in 2012

201. On February 21, 2012, Mylan filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2011 (the "February 21, 2012 10-K"). For the quarter, Mylan reported net income of $129.49 million, or $0.30 per diluted share, on revenue of $1.53 billion, compared to net income of $19.85 million, or $0.01 per diluted share, on revenue of $1.43 billion for the same period in the prior year. For 2011, Mylan reported net income of $536.81 million, or $1.22 per diluted share, on revenue of $6.13 billion, compared to net income of $345.12, or $0.68 per diluted share, on revenue of $5.45 billion for 2010. The February 21, 2012 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Coury and Sheehan, stating that the financial information contained in the February 21, 2012 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

202. The statements in ¶ 201 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

203. In the February 21, 2012 10-K, Mylan also stated:

[44] Tr. of Plea Hearing at 19:12-20:1, *United States v. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id*. at 21:23-22:6 (admitting facts).

Specialty Segment

The EpiPen Auto-Injector is the number one prescribed auto-injector with over 90% market share in the U.S. and worldwide. The strength of the EpiPen brand name, quality and ease of use of the product and the promotional strength of the Dey U.S. sales force have enabled us to maintain our market share.

[. . .]

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% in prior years. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.*** We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.[45]

(Emphasis added.)

204. The statements in ¶ 203 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

205. In the February 21, 2012 10-K, Mylan also stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY

[45] Mylan incorporated by reference its risk disclosures in each of its annual reports during the Class Period into each of the subsequent quarterly reports filed by Mylan during the following year. In stating in each of its quarterly reports that no material changes had occurred to the disclosures that had been made, Mylan made the same misleading statements in each quarterly report during the Class Period that it made in the annual reports preceding them.

> DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.
>
> [. . .]
>
> The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .
>
> [. . .]
>
> [S]hould there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken . . . .

206. The statements in ¶ 205 are misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

207. On April 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2012 (the "April 26, 2012 8-K"). For the quarter, Mylan reported net income of $129.08 million, or $0.30 per diluted share, on revenue of $1.58 billion, compared to net income of $104.18 million, or $0.23 per diluted share, on revenue of $1.45 billion for the same period in the prior year. In the April 26, 2012 8-K, Mylan stated, in relevant part:

> For the quarter ended March 31, 2012, Mylan's Specialty segment reported third party net revenues of $162.3 million, an increase of $65.3 million, or 67.3%, from the comparable prior year period of $97.0 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and growth in both the overall market and Mylan's market share. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions and maintains a market share in excess of 95% in the United States.
>
> Gross profit for the quarter ended March 31, 2012 was $666.3 million and gross margins were 41.8%. In the comparable prior year period, gross profit was $590.9 million, and gross margins were 40.8%. Adjusted gross profit for the quarter ended March 31, 2012 was $760.0 million and adjusted gross margins were 48% as compared to adjusted gross profit of $681.8 million and adjusted gross margins of 47% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and favorable pricing on the EPIPEN® auto-injector, partially offset by the impact of pricing reductions in all regions of our generics segment.

208. On April 27, 2012, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the April 26, 2012 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2012 (the "April 27, 2012 10-Q"). The April 27, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the April 27, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

209. The statements in ¶¶ 207-08 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

210. In its April 27, 2012 10-Q, Mylan also stated:

> OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.
>
> [. . .]
>
> The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .
>
> [. . .]
>
> [S]hould there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken . . . .

211. The statements in ¶ 210 are misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under

the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position with "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

212. On July 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2012 (the "July 26, 2012 8-K"). For the quarter, Mylan reported net income of $138.55 million, or $0.33 per diluted share, on revenue of $1.69 billion, compared to net income of $146.45 million, or $0.33 per diluted share, on revenue of $1.57 billion for the same period in the prior year. In the July 26, 2012 8-K, Mylan stated:

> For the current quarter, Mylan's Specialty segment reported third party net sales of $198.6 million, an increase of $66.9 million, or 50.8%, from the comparable prior year period of $131.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and growth in the overall market. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.
>
> Gross profit for the three months ended June 30, 2012, was $699.2 million and gross margins were 41.3%. For the three months ended June 30, 2011, gross profit was $669.4 million, and gross margins were 42.5%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2012 was $819.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of $758.7 million and adjusted gross margins of 48% in the comparable prior year

> period. The increase in adjusted gross margins was primarily the result of favorable volume and pricing on the EPIPEN® auto-injector and new products, partially offset by the impact of unfavorable pricing in all regions of our generics segment.

213. On July 26, 2012, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the July 26, 2012 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2012 (the "July 26, 2012 10-Q"). The July 26, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the July 26, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

214. The statements in ¶¶ 212-13 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

215. In its July 26, 2012 10-Q, Mylan also stated:

> OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.
>
> [. . .]

> The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .
>
> [. . .]
>
> [S]hould there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken . . . .

216. The statements in ¶ 215 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

217. On October 25, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2012 (the "October 25, 2012 8-K"). For the quarter, Mylan reported net income of $211.26 million, or $0.51 per diluted share, on revenue of $1.80 billion, compared to net income of $156.70 million, or $0.36 per diluted share, on revenue of $1.58

billion for the same period in the prior year. In the October 25, 2012 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net sales of $294.1 million, an increase of $80.1 million, or 37.4%, from the comparable prior year period of $213.9 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.
>
> Gross profit for the three months ended September 30, 2012, was $788.5 million and gross margins were 43.6%. For the three months ended September 30, 2011, gross profit was $658.4 million, and gross margins were 41.8%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2012 was $940.6 million and adjusted gross margins were 52% as compared to adjusted gross profit of $763.9 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and the increase in sales of the EPIPEN® auto-injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

218. On October 25, 2012, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the February 27, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2012 (the "October 25, 2012 10-Q"). The October 25, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the October 25, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

219. The statements in ¶¶ 217-18 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company

would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

B. Defendants' False and Misleading Statements in 2013

220. On February 27, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "February 27, 2013 8-K"). For the quarter, Mylan reported net income of $161.96 million, or $0.39 per diluted share, on revenue of $1.72 billion, compared to net income of $129.49 million, or $0.30 per diluted share, on revenue of $1.53 billion for the same period in the prior year. For 2012, Mylan reported net income of $640.85 million, or $1.52 per diluted share, on revenue of $6.80 billion, compared to net income of $536.81 million, or $1.22 per diluted share, on revenue of $6.13 million for 2011. In the February 27, 2013 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net sales of $145.3 million, an increase of $40.6 million, or 38.8%, from the comparable prior year period of $104.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.
>
> Gross profit for the three months ended December 31, 2012, was $742.3 million and gross margins were 43.1%. For the three months ended December 31, 2011, gross profit was $644.6 million, and gross margins were 42.1%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2012 was $845.4 million and adjusted gross margins were 49% as compared to adjusted gross profit of $732.2 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America during 2012 and the increase in sales of the EPIPEN® Auto-Injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

221. On February 28, 2013, Mylan filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 27,

2013 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "February 28, 2013 10-K"). The February 28, 2013 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the February 28, 2013 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

222. The statements in ¶¶ 222-21 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

223. In the February 28, 2013 10-K, Mylan stated, in relevant part:

> *Specialty Segment*
>
> Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty's portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty's revenues are derived through the sale of the EPIPEN® Auto-Injector.
>
> The EPIPEN® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name,

> quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.
>
> . . .
>
> Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.*** We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

224. The statements in ¶ 223 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

225. In the February 28, 2013 10-K, Mylan stated, in relevant part:

> Competition
>
> Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded products that compete based on their clinical characteristics and benefits.
>
> Competitive factors in the major markets in which we participate can be summarized as follows:
>
> United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

> The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty Segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.
>
> Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty Segment business, our competitors include branded manufacturers who offer products for the treatment of COPD, severe allergies and major depressive disorder, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

226. The statements in ¶ 225 were misleading because they failed to disclose: (1) that among the primary means by which Mylan competed was through use of anticompetitive agreements, including a pay-for-delay agreement with Teva to delay entry of a generic competitor to the EpiPen, and exclusive dealing agreements with schools preventing them from purchasing products competitive with the EpiPen; (2) that Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (3) that as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (4) that while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively

inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

227. In the February 28, 2013 10-K, Mylan stated, in relevant part:

> OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.
>
> [. . .]
>
> The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .
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> [. . .]
>
> Any governmental agencies that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, ***should there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken***, and may impose civil and/or criminal sanctions.

228. The statements in ¶ 228 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under

the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position with "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

229. On May 2, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2013 (the "May 2, 2013 8-K"). For the quarter, Mylan reported net income of $106.88 million, or $0.27 per diluted share, on revenue of $1.63 billion, compared to net income of $129.08 million, or $0.309 per diluted share, on revenue of $1.58 billion for the same period in the prior year. In the May 2, 2013 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net sales of $211.6 million, an increase of $40.6 million, or 23.7%, from the comparable prior year period of $171.1 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.
>
> Gross profit for the three months ended March 31, 2013, was $693.5 million and gross margins were 42.5%. For the three months ended March 31, 2012, gross

> profit was $670.2 million, and gross margins were 42.3%. Adjusted gross profit, as further defined below, for the three months ended March 31, 2013 was $796.5 million and adjusted gross margins were 49% as compared to adjusted gross profit of $760.0 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

230. On May 2, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 2, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2013 (the "May 2, 2013 10-Q"). The May 2, 2013 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 2, 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

231. The statements in ¶¶ 229-30 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; and (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income.

232. On August 1, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2013 (the "August 1, 2013 8-K"). For the quarter, Mylan reported net income of $177.69 million, or $0.46 per diluted share, on revenue of $1.70 billion, compared to net income of $138.55 million, or $0.33 per diluted share, on revenue of $1.69

billion for the same period in the prior year. In the August 1, 2013 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net sales of $236.9 million, an increase of $30.3 million, or 14.7%, from the comparable prior year period of $206.6 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.
>
> Gross profit for the three months ended June 30, 2013, was $742.4 million and gross margins were 43.6%. For the three months ended June 30, 2012, gross profit was $702.6 million, and gross margins were 41.6%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2013 was $834.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of $819.3 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, which was offset the impact of unfavorable pricing on existing products in all regions within our Generics segment.

233. On August 1, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 1, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2013 (the "August 1, 2013 10-Q"). The August 1, 2013 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 1, 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

234. The statements in ¶¶ 232-33 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would

ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

235. On October 31, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2013 (the "October 31, 2013 8-K"). For the quarter, Mylan reported net income of $158.91 million, or $0.40 per diluted share, on revenue of $1.77 billion, compared to net income of $211.26 million, or $0.51 per diluted share, on revenue of $1.80 billion for the same period in the prior year. In the October 31, 2013 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net revenues of $357.2 million, an increase of $55.4 million, or 18.4%, from the comparable prior year period of $301.8 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.
>
> Gross profit for the three months ended September 30, 2013 was $808.5 million, and gross margins were 45.7%. For the three months ended September 30, 2012, gross profit was $793.1 million, and gross margins were 44.0%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2013 was $903.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of $940.5 million and adjusted gross margins of 52% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and higher margins on products launched in 2013, which were more than offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment, including products launched in the prior year.

236. On October 31, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 31,

2013 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2013 (the "Q3 2013 10-Q"). The Q3 2013 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the Q3 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

237. The statements in ¶¶ 235-36 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

C. Defendants' False and Misleading Statements in 2014

238. On February 27, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2013 (the "February 27, 2014 8-K"). For the quarter, Mylan reported net income of $180.20 million, or $0.45 per diluted share, on revenue of $1.80 billion, compared to net income of $161.96 million, or $0.39 per diluted share, on revenue of $1.72 billion for the same period in the prior year. For 2013, Mylan reported net income of $623.70 million, or $1.58 per diluted share, on revenue of $6.91 billion, compared to net income of $640.85 million, or $1.52 per diluted share, on revenue of $6.80 billion for 2012.

239. In the February 27, 2014 8-K, Mylan stated, in relevant part:

> For the current quarter, Mylan's Specialty segment reported third party net revenues of $176.1 million, an increase of $20.2 million, or 13.0%, from the comparable prior year period of $155.9 million. The most significant contributor to Specialty segment revenues continues to be the EpiPen® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector.
>
> Gross profit for the three months ended December 31, 2013 was $796.0 million, and gross margins were 44%. For the three months ended December 31, 2012, gross profit was $742.3 million, and gross margins were 43%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2013 was $930.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of $845.4 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were favorably impacted in the current quarter as a result of higher margins on new product introductions and favorable pricing and volume on the EpiPen® Auto-Injector. These increases were partially offset by lower gross margins on existing products primarily as a result of unfavorable pricing within the Generics segment as discussed above.

240. On February 27, 2014, Mylan also filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 27, 2014 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2013 (the "February 27, 2014 10-K"). The 2013 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the 2013 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

241. The statements in ¶¶ 238-40 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's

income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

242. In the February 27, 2014 10-K, Mylan stated, in part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty's portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty's revenues are derived through the sale of the EPIPEN® Auto-Injector.

The EPIPEN® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.

. . .

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.*** We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

243. The statements in ¶ 242 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

244. In the February 27, 2014 10-K, Mylan stated, in part:

> Competition
>
> Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.
>
> Competitive factors in the major markets in which we participate can be summarized as follows:
>
> *United States*. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.
>
> The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.
>
> Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

245. The statements in ¶ 244 were misleading because they failed to disclose: (1) that among the primary means by which Mylan competed was through use of anticompetitive agreements, including a pay-for-delay agreement with Teva to delay entry of a generic competitor to the EpiPen, and exclusive dealing agreements with schools preventing them from purchasing products competitive with the EpiPen; (2) that Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (3) that as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (4) that while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

246. In the February 27, 2014 10-K, Mylan stated, in part:

> OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.
>
> [. . .]
>
> Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making

> these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.
>
> [. . .]
>
> Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, ***should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken***, and may impose civil and/or criminal sanctions.

247. The statements in ¶ 246 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

248. On May 1, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results

for the quarter ended March 31, 2014 (the "May 1, 2014 8-K"). For the quarter, Mylan reported net income of $115.90 million, or $0.29 per diluted share, on revenue of $1.72 billion, compared to net income of $106.88 million, or $0.27 per diluted share, on revenue of $1.63 billion for the same period in the prior year. In the May 1, 2014 8-K, Mylan stated, in relevant part:

> For the three months ended March 31, 2014, Mylan's Specialty segment reported third party net sales of $194.7 million, a decrease of $16.9 million, or 8.0%, from the comparable prior year period of $211.6 million. The decrease was the result of lower sales of the EpiPen® Auto-Injector, as a result of lower volumes due to a decline in wholesaler inventory levels during the quarter, only partially offset by favorable pricing. Third party net sales in the Specialty segment were also negatively impacted in the current period as a result of the discontinuation of a contract manufacturing agreement unrelated to the EpiPen® Auto-Injector. Offsetting these declines, sales of the Perforomist® Inhalation Solution increased from the comparable prior year period as a result of favorable pricing and volume.

249. On May 1, 2014, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 1, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2014 (the "May 1, 2014 10-Q"). The May 1, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 1, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

250. The statements in ¶¶ 248-49 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's

income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

251. On August 7, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2014 (the "August 7, 2014 8-K"). For the quarter, Mylan reported net income of $152.20 million, or $0.32 per diluted share, on revenue of $1.84 billion, compared to net income of $177.69 million, or $0.46 per diluted share, on revenue of $1.70 billion for the same period in the prior year. In the August 7, 2014 8-K, Mylan stated, in relevant part:

> Specialty Segment Revenue
>
> Specialty segment reported third party net sales of $287.8 million for the quarter, an increase of 22% when compared to the prior year period. The increase was due to higher sales of the EpiPen® Auto-Injector driven by market expansion, as well as price. The effect of constant currency on Specialty segment third party net sales was insignificant. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.
>
> Total Gross Profit
>
> Adjusted gross profit was $923.4 million and adjusted gross margins were 50% as compared to adjusted gross profit of $834.2 million and adjusted gross margins of 49% in the comparable prior year period. Strong adjusted gross margins were the result of growth in the EpiPen® Auto-Injector combined with the benefits and efficiencies of Mylan's vertically integrated operating platform. These increases were offset partially by unfavorable pricing on existing products, including products launched in the prior year. GAAP gross profit for the quarter was $808.8 million and GAAP gross margins were 44% as compared to GAAP gross profit of $742.4 million and GAAP gross margins of 44% in the comparable prior year period.
>
> Total Profitability
>
> Adjusted earnings from operations for the quarter were $409.9 million, down less than 1% from the comparable prior year period. The decrease in adjusted earnings from operations was due to an increase in SG&A and R&D. The increase in SG&A was impacted by our direct-to-consumer marketing campaign for the

> EpiPen® Auto-Injector, and to a lesser extent, by increases in legal and marketing costs in the North American region of the Generics business to support anticipated new product launches. R&D was at the high end of the guidance range as we continued to progress our biologics and respiratory growth platforms. GAAP earnings from operations were $226.1 million for the quarter, a decrease of 27% from the comparable prior year period.

252. On August 7, 2014, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 7, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2014 (the "August 7, 2014 10-Q"). The August 7, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 7, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

253. The statements in ¶¶ 251-52 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

254. On October 30, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2014 (the "October 30, 2014 8-K"). For the quarter, Mylan reported net income of $499.10 million, or $1.26 per diluted share, on revenue of $2.08 billion,

compared to net income of $158.91 million, or $0.40 per diluted share, on revenue of $1.77 billion for the same period in the prior year. In the October 30, 2014 8-K, Mylan stated, in part:

> Specialty Segment Revenue
>
> Specialty segment reported third party net sales of $462.0 million for the quarter, an increase of 29% when compared to the prior year period. The increase was due to higher net sales of the EpiPen® Auto-Injector driven by increased volume and favorable pricing. The increased quarterly volume resulted from double-digit growth of the epinephrine auto-injector market. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.
>
> Total Gross Profit
>
> Adjusted gross profit was $1.13 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of $903.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. GAAP gross profit for the quarter was $1.01 billion and GAAP gross margins were 49% as compared to GAAP gross profit of $808.5 million and GAAP gross margins of 46% in the comparable prior year period.
>
> Total Profitability
>
> Adjusted earnings from operations for the quarter were $659.3 million, up 43% from the comparable prior year period. SG&A expense increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased legal and marketing costs in the North American region to support anticipated new product launches. R&D expense also increased as we continued to invest in our biologics and respiratory growth platforms. GAAP earnings from operations were $495.0 million for the quarter, an increase of 46% from the comparable prior year period.

255. On November 5, 2014, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 30, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2014 (the "November 5, 2014 10-Q"). The November 5, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that

the financial information contained in the November 5, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

256. The statements in ¶¶ 254-55 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

D. Defendants' False and Misleading Statements in 2015

257. On March 2, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "March 2, 2015 8-K"). For the quarter, Mylan reported net income of $189.20 million, or $0.47 per diluted share, on revenue of $2.08 billion, compared to net income of $180.20 million, or $0.45 per diluted share, on revenue of $1.81 billion for the same period in the prior year. For 2014, Mylan reported net income of $929.40 million, or $2.99 per diluted share, on revenue of $7.72 billion, compared to net income of $623.70 million, or $1.58 per diluted share, on revenue of $6.91 billion for 2013. In the March 2, 2015 8-K, Mylan stated, in part:

> Specialty Segment Revenue
>
> Specialty segment reported third party net sales of $242.7 million for the quarter, an increase of 38% when compared to the prior year period. The increase was due to higher net sales of the EpiPen® Auto-Injector driven by increased volume and favorable pricing. The increased quarterly volume resulted from continued growth

> of the epinephrine auto-injector market. Importantly, the EpiPen® Auto-Injector became Mylan's first product to reach $1 billion in annual net sales in 2014.
>
> Total Gross Profit
>
> Adjusted gross profit was $1.12 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of $930.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. GAAP gross profit for the quarter was $969.0 million and GAAP gross margins were 47% as compared to GAAP gross profit of $795.9 million and GAAP gross margins of 44% in the comparable prior year period.
>
> Total Profitability
>
> Adjusted earnings from operations for the quarter were $606.0 million, up 34% from the comparable prior year period. SG&A expense increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased infrastructure costs. R&D expense also increased as we continued to invest in our biologics and respiratory growth platforms. GAAP earnings from operations were $392.5 million for the quarter, an increase of 44% from the comparable prior year period.

258. On March 2, 2015, Mylan also filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the March 2, 2015 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "March 2, 2015 10-K"). The March 2, 2015 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the March 2, 2015 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

259. The statements in ¶¶ 257-58 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would

ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

260. In the March 2, 2015 10-K, Mylan stated, in part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. During 2014, the EpiPen® Auto-Injector became the first Mylan product to reach $1 billion in annual net sales.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

[. . .]

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed non-innovator products, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed innovator or single-source products require manufacturers to rebate the greater of approximately 23% (up from 15%) of the***

> ***average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.*** We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

261. The statements in ¶ 260 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

262. In the March 2, 2015 10-K, Mylan stated, in part:

> Competition
>
> Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.
>
> Competitive factors in the major markets in which we participate can be summarized as follows:
>
> *United States.* The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.
>
> The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.
>
> Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant

> barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

263. The statements in ¶ 262 were misleading because they failed to disclose: (1) that among the primary means by which Mylan competed was through use of anticompetitive agreements, including a pay-for-delay agreement with Teva to delay entry of a generic competitor to the EpiPen, and exclusive dealing agreements with schools preventing them from purchasing products competitive with the EpiPen; (2) that Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (3) that as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (4) that while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

264. In the March 2, 2015 10-K, Mylan stated, in part:

> OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.
>
> [. . .]

> Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.
>
> [. . .]
>
> Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, ***should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken***, and may impose civil and/or criminal sanctions.

265. The statements in ¶ 264 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to

investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

266. On May 5, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2015 (the "May 5, 2015 8-K"). For the quarter, Mylan reported net income of $56.60 million, or $0.13 per diluted share, on revenue of $1.87 billion, compared to net income of $115.90 million, or $0.29 per diluted share, on revenue of $1.72 billion for the same period in the prior year. In the May 5, 2015 8-K, Mylan stated, in relevant part:

> Specialty Segment Revenue
>
> Specialty segment reported third party net sales of $211.1 million for the quarter, an increase of 8% when compared to the prior year period. This increase was primarily due to higher net sales of the EpiPen® Auto-Injector driven by increased volume.
>
> [. . .]
>
> Total Profitability
>
> Adjusted earnings from operations for the quarter were $429.7 million, up 9% from the comparable prior year period. R&D expense increased primarily from the continued investment in our biologics and respiratory growth programs. SG&A expense increased from the prior year period as a result of increased costs related to acquired businesses and increased selling and marketing costs, primarily stemming from the EpiPen® Auto-Injector direct-to-consumer marketing campaign. GAAP earnings from operations were $159.3 million for the quarter, a decrease of 33% from the comparable prior year period. This decrease in earnings from operations during the current quarter was primarily the result of increased acquisition related costs and increased amortization expense as a result of the acquisition of the EPD Business.

267. On May 8, 2015, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 5, 2015 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31,

2015 (the "May 8, 2015 10-Q"). The May 8, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 8, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

268. The statements in ¶¶ 266-67 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

269. In its May 8, 2015 10-Q, Mylan made the following statements:

> OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.
>
> Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.
>
> Any governmental agencies or authorities that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality,

> or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken, and may impose or pursue civil and/or criminal sanctions.

270. The statements in ¶ 269 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

271. On August 6, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2015 (the "August 6, 2015 8-K"). For the quarter, Mylan reported net income of $167.80 million, or $0.32 per diluted share, on revenue of $2.37 billion,

compared to net income of $125.20 million, or $0.32 per diluted share, on revenue of $1.84 billion for the same period in the prior year. In the August 6, 2015 8-K, Mylan stated, in part:

> Specialty Segment Revenue
>
> Specialty segment reported third party net sales of $301.9 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to growth across the segment, including higher volumes of the EpiPen® Auto-Injector.

272. On August 6, 2015, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 6, 2015 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2015 (the "August 6, 2015 10-Q"). The August 6, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 6, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

273. The statements in ¶¶ 271-72 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

274. On August 6, 2015, in Mylan's Q2 2015 Earnings Call, Defendant Sheehan cited "increased margins on existing [generic] products in North America," and noted "positive

pricing in the North America," even as Mylan experienced "mid-single-digit price declines in Europe . . . and low-single-digit price in the rest of world."

275. The statements in ¶ 274 were misleading because they failed to disclose that Mylan's margins were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

276. On October 30, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2015 (the "October 30, 2015 8-K"). For the quarter, Mylan reported net income of $428.60 million, or $0.83 per diluted share, on revenue of $2.70 billion, compared to net income of $499.10 million, or $1.26 per diluted share, on revenue of $2.08 billion for the same period in the prior year. In the October 30, 2015 8-K, Mylan stated, in part:

> Specialty Segment Revenues
>
> Specialty segment reported third party net sales of $437.8 million for the quarter, a decrease of 5% when compared to the prior year period. This decrease was primarily due to a lower average net selling price for the EpiPen® Auto-Injector as a result of competitive market conditions.

277. On October 30, 2015, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 30, 2015 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2015 (the "October 30, 2015 10-Q"). The October 30, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the October 30, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

278. The statements in ¶¶ 276-77 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified

the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

E. Defendants' False and Misleading Statements in 2016

279. On February 10, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "February 10, 2016 8-K"). For the quarter, Mylan reported net income of $194.60 million, or $0.38 per diluted share, on revenue of $2.49 billion, compared to net income of $189.20 million, or $0.47 per diluted share, on revenue of $2.08 billion for the same period in the prior year. For 2015, Mylan reported net income of $847.60 million, or $1.70 per diluted share, on revenue of $9.43 billion, compared to net income of $929.40 million, or $2.34 per diluted share, on revenue of $7.72 billion for 2014.

280. In the February 10, 2016 8-K, Mylan stated, in part:

> Specialty Segment Revenues
>
> Specialty segment reported third party net sales were $254.1 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to higher net sales of the EpiPen® Auto-Injector due to higher volumes, but with the same net payor pricing dynamics that existed throughout 2015.
>
> [. . .]
>
> Specialty segment reported third party net sales of $1.20 billion for the year, an increase of 1% when compared to the prior year. This increase was partially due to higher volumes of the EpiPen® Auto-Injector, which was offset by lower pricing. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached $1 billion in annual net sales for

> the second year in a row. In addition, sales of the Perforomist® Inhalation Solution and ULTIVA® increased by double digit percentage points from the prior year.

281. On February 16, 2016, Mylan filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 10, 2016 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "February 16, 2016 10-K"). The February 16, 2016 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the February 16, 2016 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

282. The statements in ¶¶ 280-81 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

283. In the February 16, 2016 10-K, Mylan stated, in relevant part:

> Competition
>
> Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as branded companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a branded manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

284. The statements in ¶ 283 were misleading because they failed to disclose: (1) that among the primary means by which Mylan competed was through use of anticompetitive agreements, including a pay-for-delay agreement with Teva to delay entry of a generic competitor to the EpiPen, and exclusive dealing agreements with schools preventing them from purchasing products competitive with the EpiPen; (2) that Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (3) that as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (4) that while absent anti-competitive conduct, "the U.S. pharmaceutical

marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

285. In the February 16, 2016 10-K, Mylan stated, in relevant part:

> Specialty Segment
>
> Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. For the year ended December 31, 2015, Specialty third party net sales were $1.20 billion. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached $1 billion in annual net sales for the second year in a row.
>
> The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® Auto-Injector brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.
>
> [. . .]
>
> Medicaid, a U.S. federal healthcare program, requires pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. ***Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer's price and, effective 2017, adjusted by the Consumer Price Index-Urban (the "CPI-U") based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufactures to the rebate the greater of approximately 23% of the average***

> ***manufacturer's price or the difference between the average manufacturer's price and the best price adjusted by the CPI-U based on certain data.*** We believe that federal or state governments will continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

286. The statements in ¶ 285 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

287. In the February 16, 2016 10-K, Mylan stated:

> OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTHCARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.
>
> [. . .]
>
> Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal healthcare programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable government agencies . . . ."
>
> [. . .]
>
> Should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a government authority may take a position contrary to a position we have taken . . . .

288. The statements in ¶ 287 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex

and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

289. On May 3, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2016 (the "May 3, 2016 8-K"). For the quarter, Mylan reported net income of $13.90 million, or $0.03 per diluted share, on revenue of $2.19 billion, compared to net income of $56.60 million, or $0.13 per diluted share, on revenue of $1.87 billion for the same period in the prior year. In the May 3, 2016 8-K, Mylan stated, in relevant part:

> Specialty Segment Revenues
>
> Specialty segment reported third party net sales were $247.9 million for the quarter, an increase of 17% when compared to the prior year period. This increase was primarily the result of higher volumes of the EpiPen® Auto-Injector and higher sales of the Perforomist® Inhalation Solution.

290. On May 3, 2016, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 3, 2016 8-

K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2016 (the "May 3, 2016 10-Q"). The May 3, 2016 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Campbell, stating that the financial information contained in the May 3, 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

291. The statements in ¶¶ 289-90 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

292. On August 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 8-K"). For the quarter, Mylan reported net income of $168.40 million, or $0.33 per diluted share, on revenue of $2.56 billion, compared to net income of $167.80 million, or $0.32 per diluted share, on revenue of $2.37 billion for the same period in the prior year.

293. In the August 9, 2016 8-K, Mylan stated, in relevant part:

> Specialty segment third party net sales were $402.5 million for the quarter, an increase of 33% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

[. . .]

> Specialty segment third party net sales were $650.4 million for the six months ended June 30, 2016, an increase of 27% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

294. On August 9, 2016, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 9, 2016 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 10-Q"). The August 9, 2016 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Parks, stating that the financial information contained in the August 9, 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

295. The statements in ¶¶ 293-94 were misleading because they failed to disclose: (1) that Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases; (2) that this knowing misclassification created an acute risk that the Company would be required to pay steep regulatory fines as a penalty for its illegal conduct, which would ultimately be deducted as a charge against the firm's reported net income; and (3) Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.

296. Throughout the Class Period, Mylan included the following statement in its Code of Conduct and Business Ethics: "Mylan is committed to complying with applicable antitrust and fair competition laws."[46]

297. The statements in ¶ 296 were misleading because they failed to disclose: (1) that Mylan actively was not complying with applicable antitrust and fair competition laws; (2) that Mylan competed through use of anticompetitive agreements, including a pay-for-delay agreement with Teva to delay entry of a generic competitor to the EpiPen, and exclusive dealing agreements with schools preventing them from purchasing products competitive with the EpiPen; and (3) that Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs.

VIII. LOSS CAUSATION

298. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Classes.

299. Throughout the Class Period, the price of the Company's securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants' materially false and misleading statements and omissions identified herein.

300. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have

[46] Mylan, *Code of Business Conduct and Ethics*, at 24, *available at* https://www.mylan.com/-/media/mylancom/files/code%20of%20business%20conduct%20and%20ethics.pdf (last visited Mar. 20, 2017)

been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing investors' losses.

301. Mylan's failure to disclose the fraudulent activity artificially inflated the value of Mylan's shares and/or maintained those shares at an artificially high level, and the revelation and/or materialization of this information and/or the risks concealed by Mylan's fraud resulted in substantial losses to both the NASDAQ Investor Class members and the TASE Investor Class members.

A. August 19-24, 2016

302. On August 17, 2016, at 6:42PM EST, NBC News published an article titled, "EpiPen Price Hike Has Parents of Kids with Allergies Scrambling Ahead of School Year" highlighting the price increases in the EpiPen over the prior years.[47]

303. On August 19, 2016 at 6:13PM EST, NBC News published an article titled "Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers 'Vultures'" stating, "A growing chorus is calling on the Mylan pharmaceutical company to justify its price hikes on EpiPens."[48]

304. On August 20, 2016, Senator Amy Klobuchar of Minnesota, the top Democrat on the Judiciary Committee's antitrust subcommittee, publicly called for a hearing to investigate "the enormous increase in the price of EpiPens."[49]

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[47] Ben Popken, *EpiPen Price Hike Has Parents of Kids With Allergies Scrambling Ahead of School Year*, NBC News (Aug. 17, 2016), *available at* http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrambling-ahead-school-n633071.

[48] Ben Popken, *Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers 'Vultures,'* NBC News (Aug. 19, 2016), *available at* http://www.nbcnews.com/business/consumer/martin-shkreli-weighs-epipen-scandal-calls-drug-makers-vultures-n634451.

[49] Amy Klobuchar, Klobu*char Calls for Judiciary Hearing and Investigation Into at Least 400 Percent Increase of EpiPen Packs* (Aug. 20, 2016), *available at* https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-judiciary-hearing-and-investigation-into-at-least-400-percent-increase-of-epipen-packs.

305. On August 22, 2016, Senator Charles Grassley of Iowa, Chairman of the Senate Judiciary Committee, sent a letter to Heather Bresch, which was published the same day.[50] The letter stated Mr. Grassley was "concerned that the substantial price increase could limit access to a much-needed medication" and requested additional information on the price increases. Also on August 22, 2016, Senator Klobuchar sent a letter to the FTC requesting an investigation into Mylan's price increase on the EpiPen. [51]

306. On August 24, 2016, The New York Times published an article titled, "Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic," in which it stated that the company's history of pricing the product highlights a common tactic in the drug industry: sharply raising prices in the years just before a generic competitor reaches the market.[52]

307. On this news and other similar stories, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell $6.17, or 12.51% between August 19 and August 24, 2016 to close at $43.15 on August 24, 2016.[53] Specifically, Mylan's share price fell $0.66, or 1.34% on August 19, $0.76, or 1.56% on August 22, $2.28, or 4.76% on August 23 and $2.47, or 5.41% on August 24, 2016.

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[50] Letter from Charles E. Grassley, U.S. Senator, to Heather Bresch, CEO Mylan N.V. (Aug. 22, 2016), *available at* https://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20(EpiPen).pdf.

[51] Amy Klobuchar, *Klobuchar Calls for FTC Investigation of Mylan Pharmaceuticals for Possible Antitrust Violations in Light of Dramatic Price Increase of EpiPen Packs*, News Release (Aug. 22, 2016), *available at* https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-ftc-investigation-of-mylan-pharmaceuticals-for-possible-antitrust-violations-in-light-of-dramatic-price-increase-of-epipen-packs.

[52] Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, The New York Times (Aug. 24, 2016), *available at* https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?_r=0.

[53] All quoted price drops in this complaint refer to drops in the share price of Mylan on NASDAQ. Substantially similar drops in the share price of Mylan on TASE occurred on or around the dates referenced in this section, and for the same or substantially the same reasons the drops in the share price of Mylan on NASDAQ occurred.

B. September 2, 2016

308. On September 2, 2016, *Inside Health Policy* published an article stating that the CMS had "informed Mylan that [the Company] incorrectly classified EpiPen as a generic under the Medicaid rebate program, which caused financial consequences for federal and state governments by reducing the amount of quarterly rebates Mylan owed for its product."[54]

309. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell $1.95, or 4.65%, to close at $39.97 on September 2, 2016.

C. October 5, 2016

On October 5, 2016, *Bloomberg* reported that CMS had issued a letter stating that Mylan had for years overcharged Medicaid to buy the Company's EpiPen shot, despite being told that the Company needed to provide larger discounts under the law. The CMS letter stated that from 2011 to 2015, the U.S. Medicaid health program spent approximately $797 million on EpiPens, including rebates of roughly 13%, rather than the discount of 23.1% that the U.S. should have received. The letter stated that the government had previously "expressly told Mylan that the [EpiPen] product is incorrectly classified."[55]

310. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell $1.19, or 3.13%, to close at $36.84 on October 6, 2016.

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[54] Inside Health Policy, *CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset* (Sept. 2, 2016), *available at* https://insidehealthpolicy.com/daily-news/cms-tells-mylan-it-incorrectly-classified-epipen-pay-lower-medicaid-rebates-lawmakers.

[55] Robert Langreth, *Mylan Accused by U.S. of Overcharging Medicaid for EpiPen*, Bloomberg News (Oct. 5, 2016), *available at* https://www.bloomberg.com/news/articles/2016-10-05/mylan-overcharged-u-s-on-epipen-for-years-u-s-says.

D. October 7, 2016

311. On October 7, 2016, Evercore ISI released an analysis suggesting that Mylan may have overcharged the national Medicaid system over $707 million on its purchases of EpiPen between 2011 to 2015.[56] On the same day, Mylan announced that it had agreed to pay $465 million to settle the DOJ's investigation into Mylan's classification of the EpiPen for the purposes of the MDRP.[57]

312. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell $0.90, or 2.44%, to close at $35.94 on October 7, 2016.

E. October 12, 2016

313. On October 11, 2016, at 6:40PM EST, CNBC reported that an Evercore ISI analyst had concluded that the alleged settlement agreement Mylan announced on October 7, 2016 "ha[d] a $120 million question attached to it," since Medicaid was projected to purchase $120 million in EpiPens during a six month grace period provided for under the alleged settlement agreement, and the details of the rebate terms governing those six months were not made public.[58]

314. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell $1.24, or 3.24%, to close at $37.07 on October 12, 2016.

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[56] Dan Managan, *Underpayments on EpiPen Rebates to Medicaid Could Top $700 million*, CNBC News (Oct. 7, 2016), available at http://www.cnbc.com/2016/10/07/underpayments-on-epipen-rebates-to-medicaid-could-top-700-million-dollars.html.

[57] Press Release, *Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector* (Oct. 7, 2016), *available at* http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector

[58] Dan Managan, *Mylan's Grace Period for EpiPen Rebates Could Cost Medicaid up to $120 Million*, CNBC News (Oct. 11, 2016), *available at* http://www.cnbc.com/2016/10/11/mylans-grace-period-for-epipen-rebates-could-cost-medicaid-up-to-120-million.html

F. November 3, 2016

315. On November 3, 2016, Bloomberg News reported that U.S. DOJ prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion. [59]

316. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result shares of Mylan fell $2.53, or 6.9% to close at $34.14 on November 3, 2016.

G. November 10, 2016

317. On November 10, 2016, reports emerged that an Evercore SIS analyst had estimated that Mylan could face liability between $380 million and $770 million under the DOJ's price collusion investigation, and that the DOJ could impose industry-wide fines in excess of $1 billion.[60]

318. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares dropped $0.64, or 1.64% to close at $38.28 on November 10, 2016.

H. December 14, 2016

319. On December 14, 2016, Bloomberg News reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of

[59] David McLaughlin and Caroline Chen, *U.S. Charges in Generic-Drug Probe to Be Filed by Year-End*, Bloomberg News (Nov. 3, 2016), *available at* https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end.

[60] *See, e.g.*, Eric Sanowsky, *DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says*, FiercePharma (Nov. 10, 2016), *available at* http://www.fiercepharma.com/pharma/doj-s-price-fixinginvestigation-could-lead-to-sizable-liabilities-analyst-says.

commercial operations, were "preparing to plead guilty to price-fixing charges," in a scheme that involved unnamed executives from Mylan.[61]

320. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares dropped $0.61, or 1.6% to close at $37.69 on December 14, 2016.

I. January 10, 2017

321. On January 10, 2017, The Philadelphia Inquirer reported that "Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, admitted to conspiring to manipulate prices of a popular antibiotic and a diabetes medication between April 2013 and December 2015."[62]

322. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result between January 10, 2017 and January 12, 2017, Mylan shares dropped $2.18 or 5.6% to close at $36.77 on January 12, 2017.

[61] Tom Schoenberg, David McLaughlin and Sophia Pearson, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg News, (Dec. 14, 2016), *available at* https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.

[62] Jeremy Roebuck, *Ex-N.J. Pharma Execs Admit to Fixing Generic Drug Prices*, The Philadelphia Inquirer (Jan. 10, 2017), *available at* http://www.philly.com/philly/news/new_jersey/20170110_Ex-N_J__pharma_execs_admit_to_fixing_generic_drug_prices.html.

J. January 30, 2017

323. On January 30, 2017, Bloomberg News reported that Mylan had received a request for information from the FTC regarding whether Mylan had engaged in anticompetitive activity, including entering pay-for-delay agreements, relating to the EpiPen.[63]

324. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares fell $0.32, or 0.87% to close at $36.34 on January 30, 2017.

IX. ADDITIONAL SCIENTER ALLEGATIONS

325. Mylan, Bresch, Coury, Campbell, Parks and Sheehan each knew about the false and misleading nature of the statements discussed above, or at a minimum were reckless for not knowing these matters.

326. Defendants Coury and Bresch served successively as CEO of Mylan during the Class Period. Defendants Sheehan and Parks served successively as CFO of Mylan during the Class Period. Campbell served as Chief Accounting Officer during the Class Period. Coury and Bresch, by virtue of their responsibilities and activities as CEO of the Company, Sheehan and Parks, by virtue of their responsibilities and activities as CFO, and Campbell, by virtue of his responsibilities and activities as the Company's Chief Accounting Officer, were privy to, and participated in the fraudulent conduct described in this Complaint.

327. As Mylan's sales of the EpiPen accounted for a significant and material portion of Mylan's revenue and operating profits throughout the Class Period, Mylan's sales of EpiPen were part of Mylan's core business. During the Class Period, EpiPen was responsible for between 28% and 95% of Mylan's operating profits. Because Mylan's sales of EpiPen were

[63] David McLaughlin, Sara Forden and Jared Hopkins, *Mylan Faces U.S. Antitrust Investigation on EpiPen*, Bloomberg News, at 1 (Jan. 30, 2017), *available at* https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices.

part of Mylan's core business, the Individual Defendants, and through them Mylan, would have had robust knowledge of significant aspects of those sales, and knew about or recklessly disregarded Mylan's misclassification of the EpiPen for the purposes of the MDRP, and Mylan's anticompetitive agreements with Teva and schools.

328. The Individual Defendants repeatedly attested to their robust knowledge of Mylan's sales and pricing activity. Each of Bresch, Coury, Parks, Sheehan and Campbell signed certifications in Mylan's SEC filings pursuant to SOX in each quarter during which they held the roles of CEO, CFO or Chief Accounting Officer. In each of these certifications, the Individual Defendants each stated that the information contained in them was accurate and not misleading. These attestations required robust knowledge of Mylan's financial statements and the bases of these financial statements, including the bases for Mylan's statements of its sales, revenue and drug pricing. These attestations also required robust knowledge of Mylan's statements of risk factors and whether those risks had materialized.

329. Bresch, Coury, Parks, Sheehan and Campbell likewise repeatedly attested to their understanding of the rule for classifying drugs for the purposes of the MDRP, and understood this rule to require products, like the EpiPen, that were marketed under NDAs to be classified as brand drugs. In SEC filings throughout the Class Period, each of Bresch, Coury, Parks, Sheehan and Campbell certified that the following statement was accurate and not misleading:

> The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% in prior years. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

330. This statement makes clear that the Individual Defendants knew or recklessly disregarded the simple rule for the proper classification of the EpiPen for the purposes of the MDRP, knew the financial consequences of that classification for Medicaid and Mylan, and yet continued to classify the EpiPen as if it were marketed under an ANDA and subject to only a 13% rebate. The Individual Defendants each knew or recklessly disregarded that they were marketing their single most important drug, the EpiPen, as a brand name drug under an NDA, rather than as a generic drug under an ANDA, and so knew that under the simple rule they certified to be accurate and not misleading, the EpiPen was misclassified.

331. The Individual Defendants likewise knew or recklessly disregarded Mylan's misclassification of the EpiPen because CMS repeatedly informed Mylan that Mylan was misclassifying the EpiPen for purposes of the MDRP, and because in November 2014, the DOJ had opened an investigation into "whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."

332. As stated above, CW has confirmed that Defendants Coury and Bresch, as successive CEOs, and Defendants Sheehan and Parks, as successive CFOs, each knew of and approved all material pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan's Morgantown, West Virginia facility, which at the time was the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. In CW's role as Director of Costing, CW worked directly with Defendant Sheehan. CW also attended company-wide meetings that were

led by Defendant Bresch and concerned company initiatives. CW also worked with Mylan President Tony Mauro on costing decisions.

333. CW stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. "[Price] was always a topic." CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW, Defendants Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For example, "[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at." CW understood the "anthrax antibiotic" in question to be doxycycline.

334. The numerous investigations and legal actions into Mylan's misclassification of the EpiPen and price fixing further evidence Mylan's scienter. In addition to multiple, ongoing investigations by the DOJ, SEC, CMS and the United States Congress, the attorneys general of forty states have "uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States," by among others, Mylan. Mylan senior executives participated consciously and willingly in the anticompetitive conduct at issue in these investigations.

335. That Mylan and Individual Defendants Campbell and Parks agreed to settle the DOJ's investigation into Mylan's misclassification of EpiPen for purposes of the MDRP for at least $465 million evidences scienter.

336. That Mylan and the Individual Defendants knew or recklessly disregarded that Mylan, in concert with Meridian Medical Technologies and King Pharmaceuticals, agreed to give Teva a "reverse payment" in exchange for Teva's agreeing to delay introducing its generic epinephrine autoinjector into the market until 2015, evidences scienter.

337. That Mylan and the Individual Defendants knew or recklessly disregarded that Mylan entered into exclusive dealing agreements with schools under which Mylan agreed to sell the EpiPen at a discount in exchange for an agreement by the schools not to purchase any product competitive with the EpiPen, evidences scienter.

338. That the prices of the Price-Fixed Drugs increased immediately following meetings of members of generic drug companies (attended by Mylan executives, including Defendant Bresch) during which the companies, including Mylan, colluded to fix generic drug prices, evidences scienter.

X. CLASS ACTION ALLEGATIONS

339. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of two classes: (1) a class consisting of all those who purchased or otherwise acquired Mylan securities on the NASDAQ during the Class Period and who were damaged upon the revelation of the alleged corrective disclosures (the "NASDAQ Investor Class"), and (2) a class consisting of all those who purchased or otherwise acquired Mylan securities on the TASE during the Class Period and who were damaged upon the revelation of the alleged corrective disclosures (the "TASE Investor Class") (collectively, the "Classes"). Excluded from the Classes are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

340. The members of each of the Classes are so numerous that joinder of all members is impracticable. Throughout the Class Period, Mylan securities were actively traded on the NASDAQ-GS, and were actively traded on TASE between November 4, 2015 and the end of the Class Period. While the exact number of members of the Classes is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in each of the proposed Classes. Record owners and other members of the Classes may be identified from records maintained by Mylan or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

341. Plaintiffs' claims are typical of the claims of the members of the Classes, as all members of the Classes are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

342. Plaintiffs will fairly and adequately protect the interests of the members of the Classes and have retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Classes.

343. Common questions of law and fact exist as to all members of each of the Classes and predominate over any questions solely affecting individual members of each of the Classes. Among the questions of law and fact common to each of the Classes are:

(a) whether applicable securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Mylan;

(c) whether the Individual Defendants caused Mylan to issue false and misleading statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(e) whether the members of the Classes have sustained damages and, if so, what the proper measure of damages is.

344. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Classes may be relatively small, the expense and burden of individual litigation make it impossible for members of the Classes individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

345. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine.

346. The markets for Mylan's securities were open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Mylan's securities traded at artificially inflated prices during the Class Period. On October 30, 2015, the Company's shares on NASDAQ closed at a Class Period high of $150.94 per share. Plaintiffs and other members of the Classes purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Mylan's securities and market information relating to Mylan and have been damaged thereby.

347. During the Class Period, the artificial inflation of Mylan's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the

damages sustained by Plaintiffs and other members of the Classes. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Mylan's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Mylan and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated and maintained at artificially inflated levels at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs' and other members' of the Classes purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

348. At all relevant times, the markets for Mylan's securities were efficient market for the following reasons, among others:

(a) Mylan shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Mylan filed periodic public reports with the SEC and/or the NASDAQ and/or TASE;

(c) Mylan regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Mylan was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and

certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

349. As a result of the foregoing, the market for Mylan's securities promptly digested current information regarding Mylan from all publicly available sources and reflected such information in Mylan's share price. Under these circumstances, all purchasers of Mylan's securities during the Class Period suffered similar injury through their purchase of Mylan's securities at artificially inflated prices, and a presumption of reliance applies.

350. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) because the Classes' claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery.

XI. NO SAFE HARBOR

351. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-

looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Mylan who knew that the statement was false when made.

XII. FIRST CLAIM

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Brought by Plaintiffs on Behalf of the NASDAQ Investor Class Against All Defendants for Purchases Made on the NASDAQ)

352. Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

353. Throughout the Class Period, Mylan's common shares were listed on the NASDAQ.

354. During the Class Period, Defendants made, disseminated or approved the false and misleading statements specified above. Defendants knew that such statements, when made, were false and misleading, or were reckless in their disregard as to the truth of such statements, which contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

355. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs in connection with its purchases of Mylan securities during the Class Period.

356. Plaintiffs have suffered damages in that, in reliance on Defendants' statements and the integrity of the market, they paid artificially inflated prices for Mylan's securities. Plaintiffs would not have purchased such securities at the prices they paid, or at all, if they had been aware that the market prices of such securities had been artificially and falsely inflated by Defendants' misleading statements.

357. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the NASDAQ Investor Class suffered damages in connection with their purchases of Mylan's securities on the NASDAQ during the Class Period.

XIII. SECOND CLAIM

For Violation of Section 20(a) of the Exchange Act
(Brought by Plaintiffs on Behalf of the NASDAQ Investor Class Against the Individual Defendants for Purchases Made on the NASDAQ)

358. Plaintiffs repeat and reallege the above paragraphs as though fully set forth herein.

359. Throughout the Class Period, Mylan's common shares were listed on the NASDAQ.

360. The Individual Defendants acted as controlling persons of Mylan within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the

decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

361. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

362. As set forth above, Mylan and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the NASDAQ Investor Class suffered damages in connection with their purchases of the Company's securities traded on the NASDAQ during the Class Period.

XIV. THIRD CLAIM

For Violation of the Israel Securities Law, 1968
(Brought by the Israeli Investor Group on Behalf of the TASE Investor Class Against All Defendants for Purchases Made on the TASE)

363. The Israeli Investor Group repeats and realleges the above paragraphs as though fully set forth herein.

364. Throughout the Class Period, Mylan's common shares were listed on the NASDAQ, and Mylan's shares were dually listed on NASDAQ and TASE beginning on November 4, 2015.

365. The TASE Investor Class's claims based on purchases of Mylan stock on the TASE on or after November 4, 2015 are based on misrepresentations and omissions by Mylan made on or after November 4, 2015.

366. Israeli securities law provides unique treatment for securities of certain firms that are "dual listed," *i.e.*, available for trading on both the TASE and the national U.S. stock markets. Mylan is thus deemed a "foreign corporation" according to § 1 of the Israeli Securities Law, 1968 (the "Securities Law"), defined as "a corporation incorporated in Israel whose securities are listed for trade on a foreign stock exchange." In adopting this arrangement, Israel applies U.S. laws and regulations, including the anti-fraud provisions of the U.S. securities laws, for enforcement of disclosure obligations. (Securities Law §§ 35T, 35EE; *Verifone Holdings, Inc.* v. *Stern*, Class Action 3912-01-08, decision rendered Nov. 16, 2008; and *Stern* v. *Verifone Holdings, Inc.*, Class Action 3912-01-08, decision rendered Aug. 25, 2011, subsequent to and in light of *Morrison v. National Australia Bank*, 130 S. Ct. 2869 (2010)). According to Israeli case law, liability for violations thereof is pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act applies to the claims arising from trades made by the Israeli Investor Group on the TASE.

367. During the Class Period, in violation of Section 10(b) of the Exchange Act and Rule 10b-5, Defendants carried out a plan, scheme, and course of conduct using the instrumentalities of interstate commerce and the mails, which was intended to and, from November 4, 2015 to the end of the Class Period did: (a) artificially inflate and maintain at

artificially high levels the market price of Mylan common stock; (b) deceive the investing public, including the Israeli Investor Group and other members of the TASE Investor Class, as alleged herein; (c) cause the Israeli Investor Group and other members of the TASE Investor Class to purchase Mylan common stock at inflated prices in reliance on Defendants' false and misleading statements made knowingly or with deliberate recklessness by Defendants; and (d) cause them losses when the truth was revealed.

368. In violation of Section 20(a) of the Exchange Act, the Individual Defendants had control over Mylan and made the material false and misleading statements and omissions alleged herein between November 4, 2015 to the end of the Class Period on behalf of Mylan, within the meaning of Section 20(a) of the Exchange Act, causing damages to the Israeli Investor Group and other members of the TASE Investor Class. By virtue of their controlling shareholder status, executive positions, board membership, and stock ownership, and their culpable participation, as alleged above, the Individual Defendants had the power to influence and control and did, directly or indirectly, influence and control the decision making of the Company, including the content and dissemination of the various statements which the Israeli Investor Group contends were false and misleading. The Individual Defendants were provided with or had unlimited access to the Company's internal reports, press releases, public filings, and other statements alleged by the Israeli Investor Group to be misleading prior to or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or cause them to be corrected.

369. Alternatively, if this Court concludes that Israeli, not U.S., law applies to the claims arising from the Israeli Investor Group's purchases of common shares on the TASE, the following provisions and causes of action apply to those claims:

(a) Regulations 3-5 of the Securities Regulations (Periodic and Immediate Reports of Foreign Corporation), 2000 promulgated under the Securities Law, 1968 (the "Securities Law") - Mylan breached its reporting obligations under the "foreign law" - namely, U.S. law - defined in § 1 of the Securities Law as "the law applying to a foreign corporation because its securities are listed for trade on a foreign stock exchange, including the rules of that foreign stock exchange." Specifically, Mylan failed to submit and publicize reports, notices, and other documents as required under U.S. law, in a timely fashion as required under U.S. law or earlier, on issues required under U.S. law. Mylan thereby caused damage to the Israeli Investor Group and the TASE Investor Class.

(b) § 36 of the Securities Law and Regulations 30, 36 of the Securities Regulations (Periodic and Immediate Statements), 1970 thereunder - Mylan failed to submit immediate reports in a timely fashion as required under Regulation 30. According to Regulation 36(a), "An [immediate] report shall provide, with respect to any event or matter that deviates from the corporation's ordinary course of business, the details of [such an event's or matter's] nature, scope or potential result which will have or could have a significant effect on the corporation; the same details will be provided with respect to any event or matter that could significantly affect the price of the corporation's securities." Moreover, even if Mylan may have delayed timely reporting pursuant to Regulation 36(b), once it became aware of rumors and other public information, it breached its obligation under Regulation 36(d) to submit an immediate report and refer therein to the correctness of the information that has

already been made public. Mylan thereby caused damage to the Israeli Investor Group and the TASE Investor Class.

(c) §§ 31-32A, 34, 38B-38C of the Securities Law - Read together, these sections impose liability, *inter alia*, on a corporation, a director of a corporation, its general manager, and a controlling shareholder thereof with regard to a misleading item that was in a report, notice or document that the corporation filed pursuant to this Law - to anyone who sold or purchased securities in the course of trading on a stock exchange or over the counter, for damage caused to them by the inclusion of a misleading item in those disclosures. A "misleading item" is defined in § 1 of the Securities Law as "including anything that is likely to mislead a reasonable investor, and any matter the omission of which is likely to mislead a reasonable investor." Specifically, § 32A(c) denies the safe harbor protection for "forward looking information" under this Section from "a party that knew that the forward-looking information would not be realized." Section 32A(d) further excludes from the safe harbor's purview "facts, figures or other details in a prospectus, opinion, report, review or certificate, as applicable, which served as a basis for forward-looking information." Defendants are liable to the Israeli Investor Group and the TASE Investor Class under these provisions.

(d) § 52K of the Securities Law - This general civil liability provision imposes liability on an issuer, the directors of the issuer, its general manager, and on a controlling shareholder of the issuer for any damage caused to a holder of the issuer's securities by virtue of the issuer's violation of the provisions of this Law or of regulations hereunder. Defendants are liable to the Israeli Investor Group under this provision.

(e) §§ 35-36 of the Torts Ordinance [New Version] - These sections impose general liability in torts for negligence towards any person where a reasonable person in like circumstances should have foreseen that in the ordinary course of things the former person may be harmed by the latter person's conduct or omission. Defendants are liable for damage caused to the Israeli Investor Group and the TASE Investor Class by the former's misrepresentations as detailed in the above paragraphs.

(f) § 63 of the Torts Ordinance [New Version] - This section imposes general liability in torts for breach of statutory duty on any person who failed to comply with a duty imposed on him according to any statute, excepting this Ordinance, where the statute, according to its correct construction, is meant for the protection or benefit of another person, the breach caused damage to that person of the kind or nature of damage meant by the statute, unless that statute was meant to exclude such remedy. Defendants are liable for damage caused to the Israeli Investor Group and the TASE Investor Class by the former's failures to comply with their duties under the Securities Law as detailed in the above paragraphs

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiffs and the other members of the Classes against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Classes their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury in this Action.

Dated: March 20, 2017

Respectfully submitted,

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