IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. MYLAN Inc.; and MYLAN SPECIALTY, L.P., Defendants.	CASE NO.: **COMPLAINT** **JURY TRIAL DEMANDED**

NATURE OF ACTION

1. Plaintiff Sanofi-Aventis U.S. LLC, ("Sanofi") brings this suit to recover damages, trebled under United States antitrust law, from the anticompetitive conduct of defendants Mylan Inc. and Mylan Specialty, L.P. (collectively "Mylan"). Mylan is and has been the dominant seller in the United States of epinephrine auto-injector ("EAI") drug devices with its product known as the EpiPen®. In 2013, Sanofi launched a competing and innovative EAI drug device in the United States with a product known as Auvi-Q®. Auvi-Q® was developed by its creators for the many patients who were not satisfied with the EpiPen®'s design and wanted a better product. As this Complaint describes, to preserve the monopoly position of their $1 billion crown jewel branded drug

product, Mylan engaged in illegal conduct to squelch this nascent competition, harming both Sanofi and U.S. consumers. Sanofi's damages arise from the hundreds of millions of dollars in lost sales of Auvi-Q® due to Mylan's unlawful conduct when Sanofi marketed the EAI drug device in the United States.

2. Anaphylaxis is a serious allergic reaction that has a rapid onset and may cause death. Anaphylaxis can result from allergic reactions to foods, pets, insects, or exposure to other allergens. The true prevalence of anaphylaxis is unknown, but millions of Americans are at risk for anaphylaxis. Epinephrine is the recognized first-line treatment for anaphylaxis. Doctors recommend that patients known to be at risk for anaphylaxis always carry an EAI drug device and be trained in its use.

3. Like Kleenex when it comes to tissues, the EpiPen® has been synonymous with the EAI drug device category. Other EAI drug devices were sold over the years but none before Auvi-Q® were seen by Mylan as a credible threat to Mylan's EpiPen® monopoly in the U.S. EAI drug device market. Which is why, in December 2012, Mylan was able to publicly tout that the EpiPen® "has been the number one prescribed epinephrine auto-injector for more than 20 years and ***constitutes more than 99% of the epinephrine auto-injector market***."[1]

[1] Mylan Press Release, "Mylan Specialty Offers Tips for Parents of Children with Life-Threatening Allergies to Help Prepare for Seasonal Celebrations" (Dec. 18, 2012), http://newsroom.mylan.com/press-releases?item=123064.

4. Auvi-Q® represented a novel and advanced EAI drug device. It was designed for the smartphone generation to be smaller and easier to carry than the EpiPen®. Auvi-Q® also included voice instructions to help patients or caregivers to administer epinephrine during a highly stressful anaphylactic episode, when they may otherwise not have been trained to use the device or might be too panicked to read the written instructions on the device.

5. When Auvi-Q® was launched in January 2013, it quickly garnered praise. Many doctors, caregivers and advocates recognized that the smaller size and different shape of Auvi-Q® made it more likely that at-risk children and adults would carry their EAI drug device, and that the voice instructions of Auvi-Q® would increase the likelihood of proper use during an emergency. The marketplace was enthusiastic about a new, innovative, EAI drug device option for the first time. As a result, Auvi-Q® quickly gained traction in the marketplace in the immediate few months after its launch.

6. Faced with this competitive threat to its EpiPen® monopoly, and seeing Auvi-Q® gaining share month-by-month after its launch, Mylan erected artificial barriers to U.S. consumers' access to and use of Auvi-Q®. In particular, Mylan offered new and unprecedented rebates to commercial insurance companies, pharmaceutical benefit managers, and state-based Medicaid agencies (collectively "third-party payors") ***conditioned exclusively*** on Auvi-Q® not being an EAI drug

device that those payors would reimburse for use by U.S. consumers. The overwhelming majority of U.S. consumers rely on prescription drug coverage for the purchase of EAI drug devices. As a result of Mylan's unlawful exclusive dealing, Auvi-Q® was blocked from nearly 50% of the EAI drug device market nationally, and the blockage was even higher in some of the largest states. Moreover, Mylan's conduct had a negative effect with doctors, caregivers, and patients which effectively blocked the sale of Auvi-Q® to countless consumers and cemented Mylan's grip on the U.S. EAI drug device market. This spillover increased the already 50% of the market that was shut out to Auvi-Q®.

7. Mylan's scheme to deprive consumers of access to Auvi-Q® was undertaken with the specific anticompetitive intent and purpose to unlawfully maintain its EpiPen® monopoly in the United States:

- Mylan took the extreme step of explicitly requiring schools to certify in writing that they would not use rival EAI drug devices as a condition of Mylan's EpiPen® discount program for schools.
- Mylan misclassified the EpiPen® to the federal and state governments and thus paid substantially less in required rebates for patients covered by Medicaid.[2] The improper rebate classification for Medicaid, in

[2] *See* Mylan Press Release, "Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector" (Oct. 7, 2016), http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector; Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden (Oct. 5, 2016), available at https://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf.

turn, allowed Mylan to subsidize its deep conditional rebates to commercial third-party payors and states.

- With knowledge of when Sanofi could begin marketing Auvi-Q®, Mylan ran up the price of the EpiPen® substantially before the launch of Auvi-Q®. The significantly higher prices ensured that, once Mylan began to offer its new, large conditional rebates from the higher price level, third-party payors would (and did) find it practically impossible to refuse these rebates that Mylan leveraged across its virtual 100% share of the EAI drug device market.

- Mylan engaged in misleading advertising and other promotional activities in order to poison the well for Auvi-Q® with doctors, key thought leaders, and consumers.

- Mylan artificially raised Sanofi's costs to market Auvi-Q®, and patients' costs to purchase Auvi-Q®, by ensuring that Auvi-Q® would be covered with a higher co-pay than the EpiPen®—if Auvi-Q® were covered by third-party payors at all.

8. Mylan's EpiPen® business practices have already been the subject of widespread federal and state government regulatory scrutiny:

- Mylan was forced to take corrective measures and remove its anticompetitive exclusivity certification as part of its EpiPen® discount program for schools.

- Mylan has announced that it has agreed to a $465 million settlement with the United States Department of Justice and other government agencies for misclassifying the EpiPen® to Medicaid.[3]

- Mylan has disclosed, and agencies have announced, that Mylan is being investigated by the U.S. Department of Justice, the U.S. Federal Trade Commission, the U.S. Securities and Exchange Commission, the New York Attorney General, and the West Virginia Attorney

[3] *Id.*

General, over Mylan's commercial practices and pricing of the EpiPen®.[4]

- Its Chief Executive Officer, Heather Bresch, has been called to testify before the U.S. Congress regarding Mylan's commercial practices and pricing of the EpiPen®.

But Mylan has never been called to task for its antitrust violations.

9. Mylan's conduct deprived U.S. consumers of a choice for EAI drug devices. Because of Mylan's exclusionary conduct, Auvi-Q®'s U.S. market share fell by nearly half, from 13% (and growing) of the national market at the end of 2013 to 7% in 2014. Yet the evidence is clear that when Sanofi had an even playing field to offer consumers an alternative to the EpiPen®, patients were enthusiastic to switch to Auvi-Q®. For patients in the United States covered by third-party payors who had Auvi-Q® on formulary at similar co-pay terms to the EpiPen®, Auvi-Q® reached over 20% market share by the end of 2013 and reached over 30% market share in 2015. Similarly, in Canada, where Mylan does not market the EpiPen® and the playing field is level with open access to drug formularies, Auvi-Q® had over 30% market share nationally in 2015. Mylan's

[4] *See* Mylan N.V., Annual Report (Form 10-K) 170-71 (Mar. 1, 2017); *see also* Gillian Mohney, *West Virginia Attorney General Investigates EpiPen Maker Mylan*, ABC News (Sept. 20, 2016), http://abcnews.go.com/Health/west-virginia-attorney-general-investigates-epipen-maker-mylan/story?id=42231963; Gillian Mohney, *EpiPen Maker Mylan Pharmaceuticals Under Investigation by NY Attorney General*, ABC News (Sept. 6, 2016), http://abcnews.go.com/Health/epipen-maker-mylan-pharmaceuticals-investigation-ny-attorney-general/story?id=41897805.

conduct in the United States cut Auvi-Q® out of key distribution channels, excluding Auvi-Q® from half of the market entirely, and suppressing Auvi-Q® in most of the remaining market. Quite simply, Mylan used its monopoly power in the U.S. EAI drug device market to exclude Auvi-Q® and maintain its monopoly.

10. Sanofi sold Auvi-Q® in the United States from January 2013 until October 2015. During that almost three year time frame, Mylan's conduct harmed both Sanofi and U.S. consumers in violation of the federal antitrust laws, specifically Section 2 of the Sherman Act, 15 U.S.C. § 2. Sanofi seeks its damages, trebled, plus interest, as well as its reasonable attorneys' fees and costs of prosecuting this action, under Section 4 of the Clayton Act, 15 U.S.C. § 15.

THE PARTIES

11. Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability company, with its principal place of business located in Bridgewater, New Jersey.

12. Defendant Mylan Inc. is a domestic pharmaceutical company which develops and distributes both generic and specialty branded pharmaceutical products. Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania. Mylan Inc. is an indirect wholly owned subsidiary of Mylan N.V. Mylan N.V.'s principal executive offices

are located in Hatfield, Hertfordshire, England and Mylan N.V. group's global headquarters are located in Canonsburg, Pennsylvania.

13. Defendant Mylan Specialty, L.P. ("Mylan Specialty") is a wholly owned subsidiary of Mylan Inc. which specializes in the development and distribution of prescription drugs for the treatment of medical conditions, such as life-threatening allergic reactions. Mylan Specialty is a limited partnership registered in the State of Delaware with places of business located at 110 Allen Road, Fourth Floor, Basking Ridge, New Jersey and 781 Chestnut Ridge Road, Morgantown, West Virginia.

14. Together, Mylan Inc. and Mylan Specialty, L.P. (collectively "Mylan") market and distribute the EpiPen® in the United States.

JURISDICTION AND VENUE

15. This court has jurisdiction over all claims asserted against defendants pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1337(a), 15 U.S.C. § 4, and 15 U.S.C. § 15.

16. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. § 1391(b) and (c). For venue purposes, defendants can be found in and transact business in this District. Mylan's anticompetitive commercial practices impacted Sanofi and U.S. consumers in this District, and elsewhere.

INTERSTATE COMMERCE

17. The creation, marketing, sale and distribution of EAI drug devices occurs in interstate commerce.

FACTUAL BACKGROUND[5]

A. Anaphylaxis is a Life-Threatening Medical Condition

18. Anaphylaxis is a serious, life-threatening allergic reaction. It can occur in anyone at any time, and is often caused by exposure to allergens, including insect stings, certain foods (such as peanuts), pets or animals, medications, or other allergens.

19. Anaphylaxis is under-recognized by both patients and health care professionals. The true rate of anaphylaxis is unknown. However, studies have estimated that up to 5.1% of the US population has a "probable" history of anaphylaxis,[6] and that 27 million people have had an anaphylactic reaction.[7] An additional 9 million people have been told that they were "at risk."[8] The American

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[5] The allegations in this Complaint are made based on Sanofi's first-hand knowledge with the exception of allegations made upon information and belief regarding certain behavior by Mylan.

[6] Robert A. Wood, MD, et al., *Anaphylaxis in America: The Prevalence and Characteristics of Anaphylaxis in the United States*, 133 J. Allergy & Clinical Immunology 461 (2014).

[7] P. Lieberman, et al., *Epidemiology of anaphylaxis*, 97 Annals Allergy, Asthma & Immunology 596 (2006); F. Estelle R. Simons, *Anaphylaxis: Recent advances in assessment and treatment*, 124 J. Allergy & Clinical Immunology 625 (2009).

[8] *Id.*

College of Allergy, Asthma and Immunology estimates there are up to 2,000 episodes of anaphylaxis per every 100,000 people in the U.S. each year.[9]

20. Mylan itself estimates that 1,500 people die from anaphylaxis every year.[10] Mylan has stated that 43 million people in the U.S. are at risk for life-threatening allergic reactions due to allergic sensitivities.[11] Mylan also has stated that "1 in 13 children [are] affected by food allergies."[12]

B. EAI Drug Devices are a Relevant Product Market as the Recognized First-Line Treatment for Anaphylaxis

21. Epinephrine is the recognized front-line treatment for anaphylaxis. The National Institute of Allergy and Infectious Diseases, one of the institutes of the National Institutes of Health, has stated that "*Epinephrine is the first-line*

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[9] *Id.*

[10] Mylan Press Release, "Get Schooled in Anaphylaxis™ Unveils Interactive Digital Resources to Educate School Communities about Potentially Life-Threatening Allergies," (Oct. 17, 2012), http://investor.mylan.com/releasedetail.cfm?releaseid=714156. *See also* Katie Thomas, *Tiny Lifesaver for a Growing Worry*, N.Y. Times (Sept. 7, 2012), http://www.nytimes.com/2012/09/08/business/mylan-invests-in-epipen-as-child-allergies-increase.html (noting that child food allergy rates are rising, and that in 2008, one in 70 children was allergic to peanuts, compared with one in 250 in 1997) (hereinafter "N.Y. Times, Tiny Lifesaver for a Growing Worry").

[11] *See* Reviewing The Rising Price Of Epipens: Hearing Before the H. Comm. on Oversight & Gov't Reform (Sept. 21, 2016) (Statement of Heather Bresch, CEO of Mylan).

[12] Letter from Mylan to Senator Charles E. Grassley (Sept. 8, 2016), https://www.grassley.senate.gov/sites/default/files/constituents/Mylan%20Response%20to%20Sen%20Grassley%209%208%2016%20(002).pdf (citing Ruchi S. Gupta, et al., *The prevalence, severity and distribution of childhood food allergy in the United States*. 128 Pediatrics e9 (2011).

treatment in all cases of anaphylaxis" (emphasis in original).[13] Delayed administration of epinephrine, even in favor of using alternative treatments for symptoms of allergic reaction, is associated with death due to anaphylaxis.

22. An EAI drug device is a device used to self-deliver a controlled dosage of epinephrine during a life-threatening allergic reaction involving anaphylaxis. An EAI drug device allows a person known to be at-risk for anaphylaxis to have a portable epinephrine injector present at all times in the case of anaphylaxis due to, for instance, insect, food, or animal exposure. Patients known to be at risk for anaphylaxis are recommended to always carry an EAI drug device and to be trained in its use.

23. EAI drug devices are often administered by first responders, caregivers (such as parents), or patients themselves. They are rarely used in medical offices or hospitals. Many patients have multiple EAI drug devices to keep in their home, school or place of work, car, and their bag or backpack.

C. Regulatory and Other Barriers to Entry Exist for EAI Drug Devices

24. The EAI drug device market in the United States is characterized by difficult entry conditions and durable barriers to entry that protected and fortified Mylan's monopoly power.

[13] Joshua A. Boyce, et al., Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel, 126 J. Allergy & Clinical Immunology S1 (2010).

25. Because EAI drug devices must be prescribed by a medical professional, there is a lengthy Food and Drug Administration ("FDA") approval process that any potential new entrants must undergo to enter the market and to show that the epinephrine used in the device is bioequivalent to the EpiPen®. Demonstrating bioequivalence to the epinephrine in the EpiPen® is not required for FDA approval, but it is an important hurdle for a new entrant to convince consumers to switch to a new EAI drug device.

26. Typically, prescriptions for EAI drug devices are infrequently refilled, usually only once per year unless there is a further need due to an anaphylactic event. Additionally, because the EpiPen® has been the dominant EAI drug device in the market for decades, most caregivers and physicians are trained on the EpiPen® and have to be trained on a new product.

27. The history of the U.S. EAI drug device market shows the significant barriers to entry in this market. Previous entrants to the market, including Twinject® and Adrenaclick™, have failed to gain significant market share. Both devices shared the EpiPen®'s basic design. Both were discontinued. Adrenaclick™ was reintroduced by 2014, but has largely failed to gain traction in the market. All of these competitors, unlike Auvi-Q®, were similar in form and function to the EpiPen®—a large "Magic Marker"-shaped device that could be cumbersome for many patients to carry.

28. Teva Pharmaceuticals is developing a generic EpiPen®. However, the Teva generic's launch was delayed by a patent infringement lawsuit filed in 2009 by the holders of the patents used by the EpiPen®, and by Teva's delays in securing FDA approval. Teva settled the patent infringement lawsuit with the EpiPen®'s patent-holders, permitting Teva to enter the market in 2015—though Teva has not yet launched its generic device due to regulatory issues. Indeed, despite the patent settlement, Mylan itself has noted that high regulatory hurdles continue to exist for Teva's generic to be listed as an AB-rated substitutable EAI drug device.[14] Indeed, Heather Bresch, Mylan's CEO, has "been pretty vocal about the fact that [she] think[s] ***the bar to get an AB-rated substitutable product is very high***."[15] Mylan also filed a citizen petition asking the FDA to refrain from approving Teva's application unless the FDA determined that Mylan's product was the "same as" Mylan's EpiPen®.[16] The FDA rejected Mylan's petition.[17] Teva has announced

[14] Without an AB-rating, even if the Teva device is approved by the U.S. Food and Drug Administration and shown to be bioequivalent to the EpiPen®, a pharmacist would not be able to automatically substitute the generic Teva EAI drug device when a patient's prescription specifies the EpiPen®. *See* U.S. Food & Drug Admin., Orange Book Preface, available at https://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm (last updated Jan. 24, 2017). In that situation, a doctor would need to write a new prescription that specifies Teva's proposed EAI drug device.

[15] Transcript, Mylan Inc., Analyst / Investor Day, at 7 (Aug. 1, 2013).

[16] U.S. Food & Drug Admin., Citizen Petition Denial Response from FDA CDER to Mylan Speciality L.P. (June 15, 2015), https://www.regulations.gov/document?D=FDA-2015-P-0181-0009.

that it aims to enter the market with a generic version of EpiPen® in late 2017 or early 2018.[18]

D. The Overwhelming Majority of U.S. EAI Drug Device Sales are Made to Patients With Coverage From Third-Party Payors

29. Access to a third-party payor's drug formulary is critical to the success of an EAI drug device. The devices are almost exclusively distributed to individual patients and caregivers rather than through hospitals or other health care providers. Further, because they are necessary, life-saving devices, patients generally will not tolerate a lengthy appeals process to get coverage if their prescribed EAI drug device is not readily available—they will simply choose the device that is covered with no hassle. Thus, market access is based almost entirely on contracts with third-party payors.

30. Pharmacy Benefit Managers ("PBMs") manage the pharmacy benefit of group health plan sponsors, such as HMO plans, self-insured employers, indemnity plans, labor union plans, and plans covering public employees. Other third-party payors include commercial health insurance providers.

31. The significant majority of patients with prescription drug insurance coverage receive their benefits through a PBM or other commercial payor.[19]

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[17] *Id.*

[18] Ransdell Pierson & Deena Beasley, *Teva says aims to launch EpiPen-like device by 2018 in U.S.*, Reuters, Sept. 9, 2016, http://www.reuters.com/article/us-teva-pharm-ind-epipen-idUSKCN11F25K.

During the 2013 to 2015 period, commercial third-party payors made up approximately 71% of the EAI drug device market in the United States.

32. Another major gateway to the EAI drug device market in the United States is through state Medicaid providers. State-based Medicaid plans, which also use drug formularies, made up an additional 16% of the EAI drug device market during the 2013 to 2015 period. Together, commercial payors and Medicaid made up nearly 90% of the EAI drug device market in the U.S. over these three years. Having access to the drug formularies of these third-party payors is crucial to entering and competing vigorously in the EAI drug device market.

33. Patients with prescription drug insurance coverage through a third-party payor typically are not freely able to choose a new payor or pick-and-choose among payors for a particular brand of drug. Many patients receive third-party payor coverage through employer-sponsored plans, which may offer coverage through a specific payor. And most plans require patients to choose coverage during a limited time period each year, and patients are unable to choose a new coverage plan until the following year.

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[19] *See*, *e.g.*, Elizabeth Dietz, *Trends in employer-provided prescription-drug coverage*, Monthly Labor Review, August 2004, at 38-39, available at https://www.bls.gov/opub/mlr/2004/08/art5full.pdf.

E. Third-Party Payors Drive EAI Drug Device Sales in the United States Based on Their Formularies

34. According to a joint report on competition in the health care industry by the U.S. Department of Justice and the Federal Trade Commission, commercial third-party payors commonly use the following "tiers" when placing drugs on formularies:[20]

- Tier 1 (T1) to Tier 3 (T3) – "The ascending rates of the co-pays are designed to create an incentive for the enrollee to prefer the lowest cost, yet clinically effective, alternative. Co-pays significantly influence drug utilization."
- "Prior Authorization" (PA) is normally reserved for drugs that treat conditions or illnesses not otherwise covered by plans, have high costs, have a high potential for abuse, or are ordered in unusual quantities.
- "Not Covered" (NC) requires patients to pay full retail price – without rebates – rather than a co-pay under their insurance plans.

35. For Medicaid, most states manage the EAI drug class with a formulary. These formularies typically do not include "tiers." Rather, drugs are either covered or not covered.

36. If an EAI drug device is blocked from formulary and listed as NC or PA, patients will not have access to that product at all, or will only have access as a last resort with prior authorization from a doctor. According to the U.S.

[20] U.S. Dep't of Justice & FTC, Improving Health Care: A Dose Of Competition, Ch. 7, IV. B (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

government, drugs are normally listed as PA only when they "treat conditions or illnesses not otherwise covered by plans, have high costs, have a high potential for abuse, or are ordered in unusual quantities."[21] EAI drug devices do not meet these criteria: they are used for the treatment of illnesses that are covered by health plans, they do not have potential for abuse, and they are ordered in a regular quantity and typically refilled once per year.

37. EAI drug devices historically were not a "managed" drug category on formularies. This means that payors' formularies typically covered all available EAI drug devices and would not list any as NC or PA. Some formularies might list EAI drug devices at different coverage tiers from T2 to T3, but would typically not exclude devices from coverage altogether. As a result, before Sanofi launched Auvi-Q® in early 2013, the EpiPen® and competing EAI drug devices were generally equally available to patients on third-party payors' drug formularies, which typically did not list EAI drug devices as NC or PA.

F. Mylan's EAI Drug Device $1 Billion Monopoly

38. The EpiPen® was originally launched in 1980. Mylan has marketed the EpiPen® in the United States since 2007.

[21] U.S. General Accounting Office, Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies (2003), available at http://www.gao.gov/new.items/d03196.pdf.

39. The EpiPen® has been the number-one prescribed EAI drug device in the United States for over 25 years. Mylan itself has admitted that the EpiPen® has effectively been the EAI drug device market, with a fixed U.S. market share consistently over 90%. For example, in December 2012, prior to Sanofi's launch of Auvi-Q®, Mylan touted that EpiPen® "has been the ***number one prescribed epinephrine auto-injector for more than 20 years and constitutes more than 99% of the epinephrine auto-injector market***."[22] On August 1, 2013 (after Auvi-Q® was released), Mylan touted to investors that the EpiPen® had a "***93.3% market share***".[23]

40. Beyond Mylan's EpiPen® market share, Mylan's monopoly power is evidenced by its ability to raise prices without any loss of sales. Since Mylan purchased the EpiPen® in 2007, it has been able to raise prices more than six-fold:

[22] Mylan Specialty Press Release, "Mylan Specialty Offers Tips for Parents of Children with Life-Threatening Allergies to Help Prepare for Seasonal Celebrations" (Dec. 18, 2012), http://newsroom.mylan.com/press-releases?item=123064.

[23] Presentation, Mylan Inc., Mylan Investor Day: Seeing is Believing, at 109 (Aug. 1, 2013).

Despite these huge price increases, Mylan's market share has remained stable at extraordinarily high levels.

41. From 2013 onward, the EpiPen® approached and ultimately surpassed the $1 billion annual revenue mark for Mylan.[24] Thus, Mylan had a strong economic motive to undertake the anticompetitive conduct that is the subject of this Complaint to protect its crown jewel branded drug product by all means necessary.

G. Other EAI Drug Devices Never Threatened Mylan's Monopoly

42. EpiPen®'s past competitors failed to gain much traction in the marketplace. The two main challengers prior to 2013, Twinject® and

[24] Mylan N.V., Annual Report (Form 10-K) 60 (Mar. 1, 2017).

Adrenaclick™, were fringe players, unable to gain any meaningful market share. Both were similar in size and shape to the EpiPen®. These other EAI drug devices were both discontinued, although Adrenaclick™ has since been re-launched by a new marketer.

H. Auvi-Q® Was an Innovative EAI Drug Device That Threatened Mylan's Monopoly

43. Auvi-Q® was created by twin brothers, Evan and Eric Edwards, who grew up with severe allergies, but often forgot to carry their EpiPens® and were not satisfied with the EpiPen®'s design. The Edwards brothers attended college and graduate school with the goal of designing a superior EAI drug device that could help save lives. Evan studied engineering in college, while Eric earned a doctorate in pharmaceutical sciences, both with an eye on their mutual goal of inventing a better EAI drug device. They worked together to help choose each other's classes, and worked with professors on their ideas.[25]

44. After graduating, the Edwards brothers created a new company, Intellijject (now known as kaléo), to finalize the development of their improved EAI drug device. The result of their life-long effort was Auvi-Q®. Upon information and belief, Mylan considered licensing Auvi-Q® from Intellijject and,

[25] Katie Thomas, *Brothers Develop New Device to Halt Allergy Attacks*, N.Y. Times (Feb. 1, 2013), https://nytimes.com/2013/02/02/business/auvi-q-challenges-epipen-with-a-new-shape-and-size.html (hereinafter, "N.Y. Times, Brothers Develop New Device to Halt Allergy Attacks").

after exploring the potential opportunity with access to confidential information, declined to bring this innovative device to market to compete with its existing EpiPen® product. Thereafter, Intellijject licensed Auvi-Q® to Sanofi in 2009 for marketing in North America.[26] Sanofi recognized that Auvi-Q® represented the first time Mylan's EpiPen® had faced branded competition from an innovative EAI drug device.

45. Auvi-Q® is a small EAI drug device with automated voice instructions. Notably, the battery that powers the voice instructions of Auvi-Q® was designed to last for several years, well beyond the one-year shelf life of the epinephrine in the device (the same epinephrine shelf life as in similar EAI drug devices). The device was also designed so that Auvi-Q®'s injection mechanism works independently of the battery and other electronic features of Auvi-Q®. That way, Auvi-Q® would not need battery power to deliver its life-saving medicine.

46. Auvi-Q® was designed to be very easy to use and to carry. Other competitors to the EpiPen®—Twinject® and Adrenaclick™—shared the basic cylindrical shape as the EpiPen®, and were a similar size. Auvi-Q® was a more compact design shaped like a smartphone or a deck of cards, unlike the EpiPen®, Twinject®, and Adrenaclick™. As a result, Auvi-Q® was easy to carry in a pocket

[26] *Id.*

or small bag. The below image shows a comparison of, from left to right, Auvi-Q®, the Twinject® protective case, the Twinject® device, and the EpiPen®:

Image from the website "Amazing and Atopic," available at http://www.amazingandatopic.com/2013/06/adrenaclick-re-launch.html (last visited April 4, 2017).

47. The relative bulk of the EpiPen® can make it difficult for some patients to always carry, and studies have shown that up to two-thirds of EpiPen® users do not carry their devices at all times.[27] Evan Edwards said that Auvi-Q® was designed as "something that I knew I was going to carry with me every single day."[28] Auvi-Q® also included audio instructions, which can help walk an unfamiliar user through the procedure in an emergency, when a trained care provider may be unavailable.

48. As part of the approval process for Auvi-Q®, the FDA determined that the epinephrine used in Auvi-Q® was bioequivalent to the epinephrine in the EpiPen®.[29] This meant that the active ingredient in both the EpiPen® and Auvi-Q® were equivalent. However, because the devices were not identical, and were designed to use different procedures, Auvi-Q® could not be substituted automatically for the EpiPen® by a pharmacist because EAI drug devices require the patient or caregiver to be trained on a particular device.

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[27] *Id*.

[28] *Id.*

[29] U.S. Food & Drug Admin., Division Memorandum, NDA No. 201739, at 2 (June 7, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201739Orig1s000SumR.pdf ("The PK trial, which was not a requirement for the application, ***demonstrated bioequivalence*** (BE) between e-cue [the brand name proposed for Auvi-Q at that time] 0.3 mg and the reference 0.3 mg product [EpiPen®] using a scaled BE approach which is an analytic approach that may be applied in situations of high intra- and inter-individual variability.").

49. Patients and doctors welcomed a new innovative product in the EAI drug device market. For example, an allergy specialist at Mount Sinai Medical Center in New York said that "people might find it easier to have [Auvi-Q®] in a pocket compared to carrying a giant Magic Marker."[30] One published study found that patients overwhelmingly preferred Auvi-Q®'s method of instruction, size, and shape vis-à-vis the EpiPen®.[31]

50. On January 28, 2013, Sanofi launched Auvi-Q®. Sanofi was already well-known in the allergy space at the time for the drug Allegra®, and it brought its resources and reputation to Auvi-Q®. Sanofi spent tens of millions of dollars promoting Auvi-Q® and educating physicians and key allergy awareness groups on the benefits of Auvi-Q®. Sanofi also hired a large sales force to compete with Mylan.

51. Sanofi matched many of Mylan's promotional programs, to maximize patients' access to Auvi-Q®. Sanofi offered a discount program for schools to have access to Auvi-Q®. Sanofi also offered coupons to cover patients' co-pays to blunt the impact of the EpiPen® being listed at a preferred T2 position on many third-

[30] N.Y. Times, Brothers Develop New Device to Halt Allergy Attacks.

[31] Carlos A. Camargo, Jr., et al., *Auvi-Q Versus EpiPen: Preferences of Adults, Caregivers, and Children*, 1 J. Allergy & Clinical Immunology: In Practice 266 (2013).

party payor drug formularies and Auvi-Q® being listed at a T3 position (when Auvi-Q® was listed).

52. Sanofi launched Auvi-Q® at price parity with EpiPen®, in part to ensure that Auvi-Q® would be treated equally with the EpiPen® in terms of patients' access. Sanofi's pre-market research had found that patients and caregivers would be willing to pay a premium over the price for the EpiPen® for the innovative Auvi-Q®, but Sanofi chose to be price-competitive with EpiPen® and avoid formularies' incentive to provide preferential treatment to a lower-priced drug.

53. Importantly, when Auvi-Q® was launched, it was generally covered (either at a T2 or T3 level) on drug formularies with key third-party payors. In general, third-party payors told Sanofi that Auvi-Q® would be covered on their formularies—in keeping with how the EAI drug device category was not restricted historically.

I. Mylan Engaged in Anticompetitive Behavior to Maintain its Monopoly

54. Mylan responded to Auvi-Q®'s initial success by taking steps to ensure that Auvi-Q® would be blocked from drug formularies going forward. Beginning around May 2013, upon information and belief, Mylan began to proactively pitch large rebates to third-party payors—30% or higher—expressly conditioned on the EpiPen® gaining exclusive position on the formulary, and

causing Auvi-Q® to now be kicked off of a drug formulary with a NC position, or be listed in a severely restricted PA position.

55. Providing rebates to third-party payors is common in the pharmaceutical industry. In some circumstances, rebates can be a form of price competition that ultimately helps to lower prices for end consumers, both when they pay for prescription drugs and when they pay health insurance premiums. Even rebates for exclusive coverage on a given third-party payor's drug formulary are not unheard of, though they are often solicited by payors. But pharmaceutical companies with monopolies for a given drug product do not—and under U.S. antitrust law, cannot—condition large rebates to block new rival drugs from key access to the market.

56. That is precisely why the timing, size, and nature of Mylan's rebates were an unprecedented combination in a number of ways. Based on pre-launch research of third-party payors, Mylan did not typically offer rebates for the EpiPen® and, where it did so, Mylan's rebates were generally low, often below 10%. After Auvi-Q® launched, Mylan began to offer much larger rebates—30% or higher. These extremely large rebates ***were conditioned on exclusivity***. In other words, Mylan offered these large rebates only if it could ensure that Auvi-Q® would not have access to the market. Combined with the EpiPen®'s extremely

high market share, these rebates created an offer that payors could not turn down, and that Sanofi could not match.

57. First, Mylan had nearly all of the approximately $1B in sales in the U.S. EAI drug device category before Auvi-Q® launched. Mylan was leveraging its durable greater-than-90% market share in getting third-party payors to exclude Auvi-Q®.

58. Second, upon information and belief, Mylan's rebates were approximately 100-200% larger (at least) than what they paid payors before Sanofi launched Auvi-Q®—if Mylan had previously offered rebates at all. Payors could not decline to cover the EpiPen® even if Mylan offered no rebates or very low rebates. This held true even after Mylan sharply increased the price of the EpiPen® before Auvi-Q® launched. Further, because of Mylan's price increases, Mylan's net prices on the EpiPen® were soon higher ***after*** it began its exclusionary rebates than they were before the rebates began. For example, if Mylan offered no rebate or very low rebates on the EpiPen® when it was priced at $200 (as it was around February 2012, when Mylan announced the settlement of patent infringement lawsuit that would allow Auvi-Q® to launch as soon as November 2012), but offered a 30% rebate on the EpiPen® when it was priced at $300 (as it was by January 2014, when Mylan's large, exclusionary rebates went into effect), Mylan's

net price after the rebate, $210, exceeded the $200 price before Mylan's large exclusionary rebates began.

59. Third, and most importantly, Mylan conditioned those rebates on Auvi-Q® being blocked and put in a NC or PA formulary position. Upon information and belief, Mylan allowed other EAI drug devices, such as the re-released Adrenaclick™, to remain on at least some third-party payors' formularies. The only competitor Mylan required be excluded was Auvi-Q®. These rebates caused third-party-payors to begin to restrict the EAI drug device category for the first time. There was no legitimate business reason for Mylan's deep conditional rebates other than to block Auvi-Q® from the market.

60. Moreover, Mylan's conditional rebates were a direct response to Auvi-Q®'s gains in share in the marketplace following its January 2013 launch, and an effort to stop Auvi-Q® in its tracks and regain its monopoly position. Mylan saw Auvi-Q® quickly gaining favor among physicians, patients, and caregivers—and gaining market share—and Mylan then proactively sought to exclude Auvi-Q® from formularies with large, unprecedented rebates conditioned on excluding Auvi-Q®. Mylan used its monopoly market share and large rebates to coerce third-party payors to choose between accepting Mylan's huge rebates to exclusively cover the EpiPen®, or foregoing those rebates to allow Auvi-Q® to compete on the market. In some cases, Mylan's offers caused third-party payors to

revisit and reverse decisions to cover Auvi-Q®, after those payors had already agreed to cover Auvi-Q® on their formularies.

61. Sanofi tried to match Mylan's rebates, but EpiPen®'s dominant market share made it irrational for third-party payors to turn down Mylan's offer. If Sanofi matched Mylan's offer and provided a 30% rebate to convince a third-party payor to list Auvi-Q® at parity with the EpiPen® at T2, but Mylan did not provide a rebate (or provided a much smaller rebate) because the third-party payor had not granted the EpiPen® exclusive coverage, then the third-party payor would have foregone the Mylan rebate on the high percentage of the EAI drug device market that was held by the EpiPen®, while only gaining the Sanofi rebate on a smaller percentage of the market. This meant that a new entrant, like Sanofi, would need to offer rebates far in excess of the 30% rebates offered by Mylan.

62. For example, Sanofi estimated that, for a typical commercial payor, if Auvi-Q® obtained a 10% U.S. EAI drug device market share, Sanofi would need to offer a 151% rebate (and lose money) to that third-party payor to compensate it for the rebates it would lose by turning down Mylan's 30% conditional rebate on its 90%-plus U.S. EAI drug device market share. At even a 15% market share, Sanofi would need to offer a nearly 100% rebate (and make no money) to match the cost of turning down Mylan's offer. Further, Mylan's repeated price increases prior to

the launch of Auvi-Q® added to Mylan's ability to offer large rebates that Sanofi, mathematically, could not match.

63. Mylan offered similar rebates to other third-party payors, such as state-based Medicaid formularies. Upon information and belief, Mylan excluded Auvi-Q® from coverage in many states due to these rebates.

64. When third-party payors saw the offer of a 30% rebate from Mylan, which again at the time had a 90%+ market share, they saw (and told Sanofi) that there was no way for Sanofi to match, as Mylan's proposed ***rebate*** far exceeded Auvi-Q®'s projected ***sales***.

65. Third-party payors confirmed to Sanofi that Mylan's dominant EpiPen® market share made it impossible for Sanofi to match Mylan's rebate. Put simply, Mylan made third-party payors a never-before-made financial offer "they could not refuse." Auvi-Q® represented a major innovation in the EAI drug device space that many patients and physicians preferred, but Mylan's exclusionary conduct kept Auvi-Q® out of patients' hands.

66. Not only did Mylan's monopoly market share make it mathematically impossible for Sanofi to match its conditional rebates, but Sanofi had no intention of trying to make similar offers to exclude the EpiPen® from patients' coverage. As discussed below, such a strategy was not feasible for a new entrant in the U.S. EAI drug device market. As a new challenger of an entrenched monopolist for a

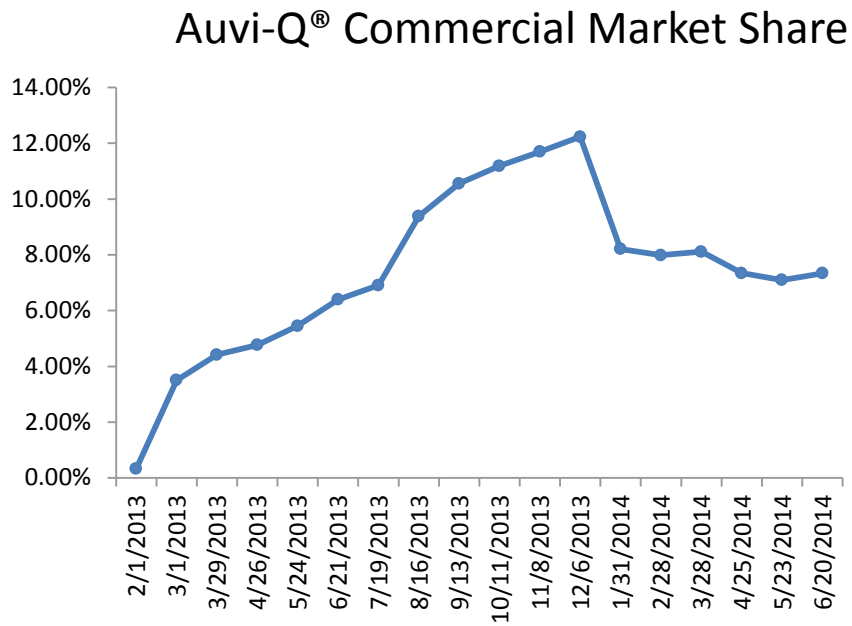
life-saving drug, Sanofi did not want to make Auvi-Q® the only option available to patients. Rather, Sanofi wanted to promote Auvi-Q® on an even playing field, and allow patients and caregivers to choose for themselves which EAI drug device they preferred.

67. Mylan's illegal conditional rebate scheme to exclude Auvi-Q® from the U.S. EAI drug device market was successful. Many of the largest third-party payors announced formulary decisions in the 2nd half of 2013 (to be effective then or as of January 1, 2014) that Auvi-Q® would not be covered, but listed as NC or PA. The majority of states manage their Medicaid drug formularies and, in most of those states, Auvi-Q® was excluded. For some of these states where Auvi-Q® was excluded, like Florida, Medicaid represents 20-25% of all EAI drug device prescriptions. These coverage decisions typically last for one or two years. Mylan blocked Auvi-Q® from about 45% of the lives covered by commercial payors in 2014. More than half of the ten largest commercial payors did not cover Auvi-Q® in 2014 as a result of Mylan's exclusionary rebates. When including coverage by all third-party payors, including Medicaid formularies, the degree of market foreclosure to Auvi-Q® was even higher.

68. One year after its launch, Mylan had blocked close to 50% of the U.S. EAI drug device market to Auvi-Q®. In certain states, where the mix of third-party

payors covering patients were over-represented by payors that did not cover Auvi-Q®, patient access to Auvi-Q® was well under 50% of the market.

69. ***Auvi-Q®'s share of the market dropped by nearly 50% in one month between December 2013 and January 2014, after all of Mylan's conditional rebates blocking Auvi-Q® took effect.*** Sanofi's U.S. commercial payor market share had grown to around 13% by December 2013. In January 2014, its share dropped to around 8%, further dropping to around 7% by May 2014:



70. Compounding the limited marketplace access, the saturation of the marketplace with these negative coverage decisions in Auvi-Q®'s launch year, even before their effective dates, strongly disincentivized doctors from prescribing Auvi-Q®. And when doctors know that half (or more) of their patients have

insurance that will not cover Auvi-Q®, most doctors will decline to prescribe Auvi-Q® to ***any*** patients, rather than take the time to cross-reference their patients' insurance coverage with payors' formularies. This slowed Auvi-Q®'s growth in 2013 before all of Mylan's anticompetitive conditional rebates took effect in 2014.

71. Mylan also engaged in other pricing practices to block Auvi-Q®. In 2013, around the time that Auvi-Q® launched, Mylan for the first time announced a $0 co-pay coupon for the EpiPen®, so that patients with prescription drug coverage would not need to pay for their EpiPens® at the pharmacy counter.[32] Sanofi also offered a $0 co-pay coupon, to match the EpiPen®. But because the EpiPen®, as the incumbent EAI drug device, was often listed at a higher coverage tier than Auvi-Q® (as Mylan touted to physicians, *see* below), the EpiPen®'s co-pay was typically much lower than Auvi-Q®'s co-pay. So Sanofi had to pay significantly more to reimburse pharmacies for the $0 co-pay for Auvi-Q® than Mylan did for the EpiPen®.

[32] *See* Mylan Press Release, "Mylan Specialty L.P. Announces 25th Anniversary Celebration of EpiPen® (epinephrine) Auto-Injector," (April 25, 2013) http://files.shareholder.com/downloads/ABEA-2LQZGT/0x0x656943/5f7bf096-4790-4556-8d58-807dd1ab362d/MYL_News_2013_4_25_General_Releases.pdf ("In recognition of this important milestone, Mylan Specialty recently introduced the 25th anniversary '$0 Co-Pay Offer.'").

J. Mylan Specifically Intended to Squash the Competitive Threat from Auvi-Q®

72. By the second half of 2013, Mylan had no doubt that it had slammed the door on Auvi-Q® by choking it off from the key distribution channels to the EAI drug device market. That is why Mylan felt so confident in touting the preferred status of the EpiPen® in the EAI drug device marketplace to its investors. Specifically, in Mylan's October 31, 2013 earnings call, Mylan CEO Heather Bresch noted that, for EpiPen® and the EAI drug device marketplace,

> "we believe we'll continue to get ***our very much disproportionate share*** around the marketplace, again, for years to come. And I think as far as pricing our formulary position, ***we are in a number one formulary position with all the major formularies and don't see any of that changing next year [i.e., 2014].***"

73. On an August 7, 2014 Mylan earnings call—before the EpiPen®'s pricing received public scrutiny—Mylan's CEO Heather Bresch did not deny that the EpiPen®'s marketing "leadership" was due to rebate payments:

> Elliot Wilbur – Needham & Company, LLC, Research Division: First question is for Heather with regard to the EpiPen franchise. Obviously, you're seeing a lot of noise in the market and a lot of shifting regarding formulary positioning. And I guess, despite the fact that EpiPen is a dominant product in the category; and sort of the price leader, it still maintained very strong formulary positioning. And I'm just curious sort of what the trend has been in rebating on the product. ***Whether that strong formulary position has come increasingly at the cost of higher rebates?***
>
> Heather Bresch: Okay. Sure, Elliot. So what I'd say, Elliot, around EpiPen, obviously, when you've got a multiple epinephrine product marketplace, it leads to a more competitive positioning both with the pharmacies, as well as payers. I think that given the breadth and scope

> of our business that we've been able to manage and to obviously remain very competitive in that structure. But with that being said, ***we're going to do whatever we need to do to really maintain that market leadership***, and like I said, and continue to look at ways that we can enhance and add to this franchise.[33]

74. The timing of Mylan's conditional rebates—commenced only after Auvi-Q® had begun to gain market share—and their unprecedented nature show that Mylan intended to re-shape the market to block a competitor. Mylan's anti-competitive intent to maintain its EpiPen® monopoly against competition from Auvi-Q® is confirmed in numerous ways:

a. Mylan's Rebates Were Designed To Be Impossible For Auvi-Q® To Match

75. As discussed above, due to the Epipen®'s monopoly market share, at a 10% market share, Sanofi would have needed to offer rebates far exceeding its revenues just to match the rebates that commercial payors would forego by turning down Mylan's conditional rebates and covering both the EpiPen® and Auvi-Q®. Even at a 15% market share, Sanofi would have had to offer rebates equaling its revenues to match the rebates from Mylan that a payor would forego.

76. Further, Sanofi did not—and could not—try to take the EpiPen®'s place as the only covered product on a formulary. It is not practically possible for a new entrant to completely and instantaneously replace an entrenched monopolist in the market for a life-saving emergency pharmaceutical. Approximately 50% of

[33] *See* Transcript, Mylan Inc., Earnings Call (Aug. 7, 2014).

EAI drug device prescriptions are refills, and pharmacists were not authorized to fill a prescription for the EpiPen® with an Auvi-Q® device, because both EpiPen® and Auvi-Q® were not substitutable for each other at a pharmacy. For the purposes of patient safety, Sanofi did not want to require patients who may not have coverage for a prescribed device to wait for a doctor to revise a prescription for a covered device, and risk not having access to the EAI drug device until the prescription can be re-written. Furthermore, Sanofi did not seek exclusive status on any formularies because: 1) it did not want to force any patients who are comfortable with the EpiPen® to switch to Auvi-Q®; 2) despite spending tens of millions of dollars educating and training patients and caregivers, Auvi-Q® had not reached 100% market awareness; and 3) Sanofi was confident that given equal access to Auvi-Q® and EpiPen®, patients would continue to choose Auvi-Q®, as was the case in the months following Auvi-Q®'s release into the market in January 2013.

b. Mylan's Strong Arming of Schools

77. As a result of high profile deaths of children in schools where no EAI drug device was available,[34] a number of state legislatures passed laws allowing school personnel to keep and administer non-student-specific EAI drug devices to

[34] *See*, *e.g.*, Ryan Jaslow, *Girl, 7, ate peanut before dying of allergic reaction at school*, CBS News (Jan. 13, 2012), http://www.cbsnews.com/news/girl-7-ate-peanut-before-dying-of-allergic-reaction-at-school/.

students during anaphylactic emergencies. In addition, in 2013, President Obama signed into law the School Access to Emergency Epinephrine Act, which encouraged more states to enact similar laws.

78. Mylan reportedly spent at least $4 million lobbying Congress to pass the School Access to Emergency Epinephrine Act,[35] and at least a million more lobbying state legislatures to pass such laws.[36] Moreover, one of the leading advocates for states to pass epinephrine access laws was Gayle Manchin, the mother of Mylan CEO Heather Bresch.[37]

79. Mylan noted that these epinephrine access laws are "a game changer in expanding access" to EAI drug devices, and has touted the importance of these programs for expanding awareness of anaphylaxis and the EpiPen® brand.[38]

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[35] Erik Larson & Jared S. Hopkins, *Mylan's EpiPen School Sales Trigger N.Y. Antitrust Probe*, Bloomberg News (Sept. 6, 2016), https://www.bloomberg.com/news/articles/2016-09-06/n-y-s-schneiderman-launches-probe-into-mylan-epipen-sales.

[36] Pauline Bartolone, *Behind The EpiPen Monopoly: Lobbying Muscle, Flailing Competition, Tragic Deaths*, Kaiser Health News (Sept. 8, 2016), http://khn.org/news/behind-the-epipen-monopoly-lobbying-muscle-flailing-competition-and-tragic-deaths/.

[37] *See* Jayne O'Donnell, *Family matters: EpiPens had high-level help getting into schools*, USA Today (Sept. 20, 2016), https://www.usatoday.com/story/news/politics/2016/09/20/family-matters-epipens-had-help-getting-schools-manchin-bresch/90435218/.

[38] Presentation, Mylan Inc., Mylan Investor Day: Seeing is Believing, (Aug. 1, 2013)

80. Both Mylan and Sanofi had programs designed to provide free or discounted EAI drug devices to schools. Only Mylan, unlike Sanofi, required that a school taking part in Mylan's discounted EpiPen® program certify in writing that the school "***will not purchase any products that are competitive products to EpiPen® Auto-Injectors***." An excerpt from Mylan's form appears below:

CERTIFICATION FORM:
EpiPen® Auto-Injectors School Discount Program

The school and/or school district identified below (the "School") hereby acknowledges and agrees that the EpiPen® (epinephrine) Auto-Injectors School Discount Program made available by Mylan Specialty L.P. ("Mylan Specialty") to the School is because it is a school and is conditioned upon the undersigned making this certification to Mylan Specialty.
The School represents and warrants to Mylan Specialty that:

(vi) the School hereby certifies that it will not in the next twelve (12) months purchase any products that are competitive products to EpiPen® Auto-Injectors;

81. There was no legitimate business reason for Mylan's contractual lock-up of schools. The sole purpose of this contractual term was to prevent schools from stocking Auvi-Q®.

82. As Mylan knows, schools located in some states with "EpiPen laws" are ***required*** to have EAI drug devices on hand in case of emergency. Public schools with limited budgets would have no choice but to accede to Mylan's contractual commitment.

83. Mylan later eliminated the requirement that schools participating in the EpiPen® School Discount Program commit to exclusively use EpiPens® against any other EAI drug device.

84. New York's Attorney General identified Mylan's school exclusivity policy as anti-competitive, and launched an investigation into Mylan's anti-competitive business practices.[39]

85. Mylan's abandonment of its school exclusivity policy constitutes consciousness of guilt. This was recognized by a number of commentators who questioned whether Mylan's exclusivity requirement with schools violated U.S. antitrust law, including University of Iowa Professor Herbert Hovenkamp, and NYU School of Law Professor Harry First.[40] Professor Hovenkamp noted that "[i]t is illegal to issue a discount on the condition the customer not acquire a competitor's goods — if the effect may be to substantially lessen competition."[41] Professor First stated that the fact that Mylan used to require that schools only purchase EpiPens® may still be problematic because "[i]t's like the bank robber saying 'Don't worry, we don't rob banks anymore,'… But if you make such a

[39] Dan Mangan, *New York attorney general launches antitrust probe of Mylan's EpiPen contracts*, CNBC (Sept. 6, 2016), http://www.cnbc.com/2016/09/06/new-york-attorney-general-launches-antitrust-probe-of-mylans-epipen-contracts.html.

[40] Ike Swetlitz & Ed Silverman, *Mylan may have violated antitrust law in its EpiPen sales to schools*, PBS Newshour (Aug. 26, 2016), http://www.pbs.org/newshour/rundown/mylan-may-violated-antitrust-law-epipen-sales-schools-legal-experts-say/.

[41] *Id*.

change, it casts doubt on why you needed to have such a requirement in the first place."[42]

c. Mylan Underpaid EpiPen® Rebates to Medicaid Which Increased Funds for Steep EpiPen® Rebates to Commercial Third-Party Payors

86. Late last year, Mylan publicly announced that it had reached a $465 million EpiPen® settlement with the Department of Justice, Department of Health and Human Services, and other agencies, related to its misclassification as a non-innovator drug.[43] Mylan also ended its plans to seek a waiver from a new FDA rule requiring Mylan to re-classify the EpiPen® as a brand-name drug.[44]

87. The Medicaid Drug Rebate Program is a partnership between the Centers for Medicare and Medicaid Services, State Medicaid Agencies, and participating drug manufacturers that helps to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. Drugs that are listed as "non-innovators" pay the lowest rebates to State Medicaid Agencies. Non-innovator status is typically reserved for drugs that are not produced or distributed under an original New Drug Application ("NDA") approved by the

[42] *Id.*

[43] Katie Thomas, *Mylan to Settle EpiPen Overpricing Case for $465 Million,* N.Y. Times (Oct. 7, 2016), https://www.nytimes.com/2016/10/08/business/epipen-mylan-justice-department-settlement.html.

[44] *Id.*

FDA—i.e. a drug that is distributed under an *abbreviated* NDA ("ANDA") or that entered the market before 1962.

88. For years, Mylan had been misclassifying the EpiPen® as a "non-innovator" drug in the Medicare and State-based Medicaid space.[45]

89. The EpiPen® did not meet these criteria, yet maintained its status on the Medicaid Drug Rebate Program as a non-innovator drug, even though the Center for Medicaid and CHIP Services "expressly told Mylan that the product is incorrectly classified."[46] This scheme enabled Mylan to amass millions of dollars each year in unpaid rebates to cash-strapped state Medicaid agencies.[47] By contrast, Sanofi properly classified Auvi-Q® as an innovator drug and paid disproportionately larger rebates to Medicaid.[48]

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[45] *See* Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden (Oct. 5, 2016), available at https://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf.

[46] *Id.*

[47] Letter from Senator Elizabeth Warren to Attorney General Loretta Lynch (Oct. 21, 2016), available at https://www.warren.senate.gov/files/documents/2016-10-21EpiPen_settlement_letter_final.pdf.

[48] *Id.* ("[M]anufacturers of brand name drugs pay a minimum 23.1 % rebate, and … refund taxpayers the difference if a brand-name drug's price rises at a pace that exceeds the inflation rate. Generic drug manufacturers pay a significantly lower rebate, equal to 13% of the drug cost, and presently pay no inflation rebate.").

90. United States Senator Elizabeth Warren's office estimated that Mylan had underpaid Medicaid rebates by $530 million.[49] Mylan therefore had access to hundreds of millions of dollars that it did not pay in rebates to the Medicaid Drug Rebate Program to pay for the rebates that it offered to third-party payors. These rebates included additional rebates, beyond those paid to the Medicaid Drug Rebate Program, to state-specific Medicaid formularies to keep Auvi-Q® from being covered by Medicaid in many states. These rebates also included the large conditional rebates to commercial third-party payors—the largest EAI drug device distribution channel—to convince them to exclude Auvi-Q® from formularies.

d. Mylan Sharply Raised the Price of EpiPen® to Absorb Deep Rebates to Commercial Payors

91. As noted above, since 2007, the EpiPen®'s price has increased by more than 500%.

92. Upon information and belief, one of Mylan's purposes for sharply raising prices—from just over $100 for a two-pack in late 2009 to around $250 for a two-pack when Auvi-Q® launched in 2013—was to allow Mylan to absorb the deep conditional discounts it offered to third-party payors to exclude Auvi-Q® from the market. Put simply, a 30% rebate on a single $100 EpiPen® two-pack equates to a $30 rebate for a rival to match, whereas a 30% rebate on a single $250 EpiPen® two-pack is $75. That is an additional $45 (or 250%) more a rival would

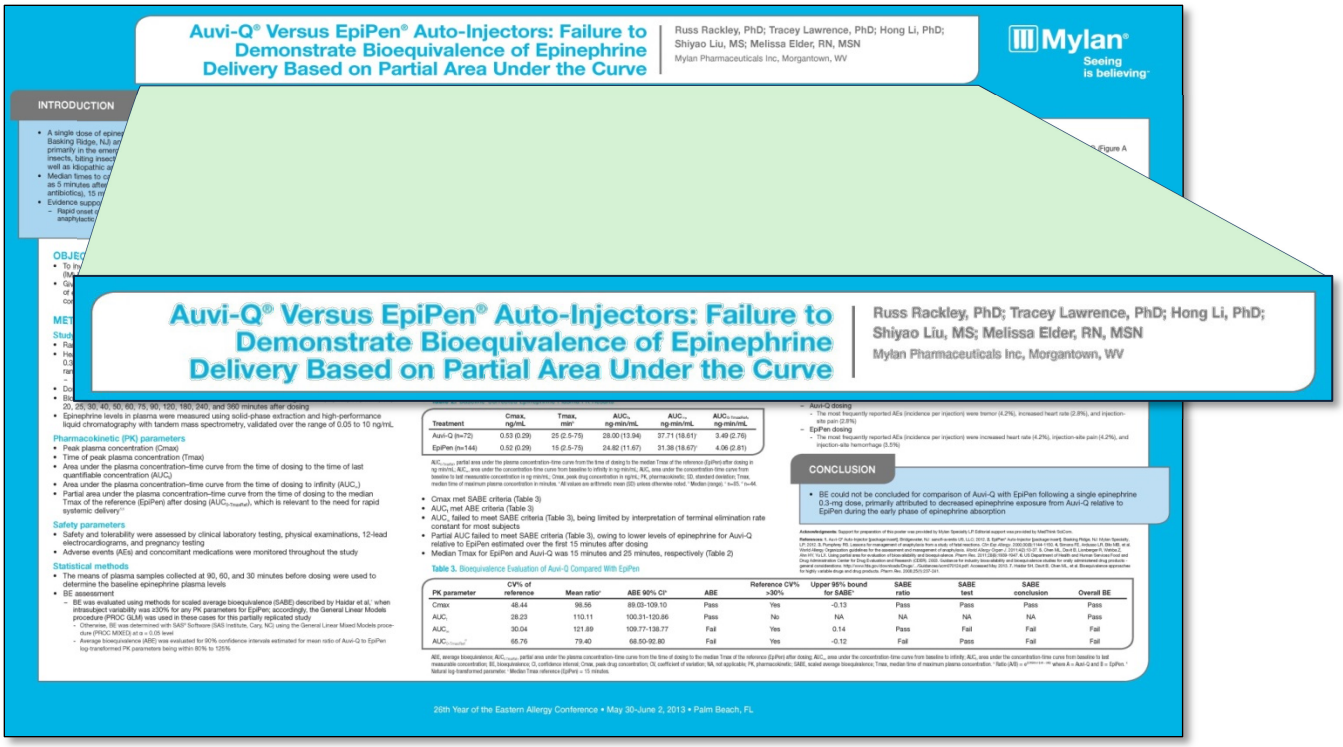
[49] *Id.*

now have to match on a single EpiPen® two-pack. That figure grows exponentially when Mylan's EpiPen® price increases are leveraged on its 90%+ share of all EAI drug device sales.

e. Mylan Engaged in Misleading Advertising and Other Promotional Activities To Harm Auvi-Q®'s Reputation

93. Mylan also created and spread misinformation about Auvi-Q® and its bioequivalence to EpiPen®. In approving Auvi-Q®, the FDA determined that the epinephrine in Auvi-Q® is bioequivalent to the epinephrine in the EpiPen®.[50] But Mylan funded and promoted a study entitled "Auvi-Q® versus EpiPen® Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve." That was a misleading title not intended for legitimate scientific debate. It was not intended to question the FDA's procedure in determining bioequivalence among EAI drug devices generally. The Mylan study was intended to undermine the FDA's conclusion that Auvi-Q® demonstrated bioequivalence to the epinephrine in the EpiPen®—and directly contradicted the FDA's conclusion. An image of Mylan's materials presenting the study is below:

[50] U.S. Food & Drug Admin., Division Memorandum, NDA No. 201739, at 2 (June 7, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201739Orig1s000SumR.pdf ("The PK trial, which was not a requirement for the application, ***demonstrated bioequivalence*** (BE) between e-cue [the brand name proposed for Auvi-Q at that time] 0.3 mg and the reference 0.3 mg product [EpiPen®] using a scaled BE approach which is an analytic approach that may be applied in situations of high intra- and inter-individual variability.").



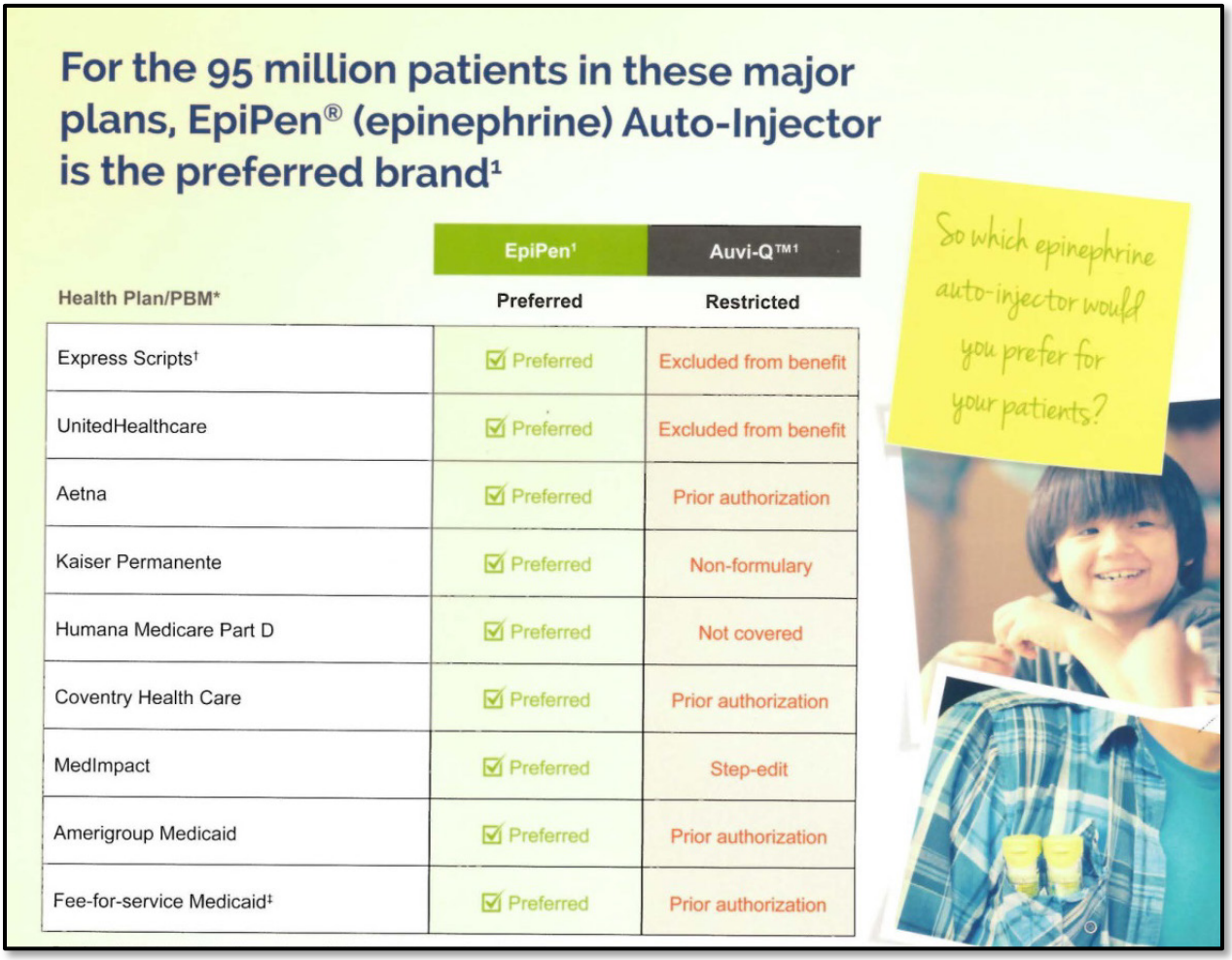
94. Mylan's presentation of this data was intended to influence the opinions of key thought leaders in the allergy field against Auvi-Q®, and to influence key allergy advocacy groups to turn against Auvi-Q®. As a result, Sanofi had to speak with key thought leaders and key allergy advocacy groups to dispel the doubt brought over Auvi-Q® as a result of Mylan seeding the marketplace with this misleading study. Sanofi also sent Mylan a letter requesting that Mylan refrain from stating or suggesting that the active ingredient in Auvi-Q® is not bioequivalent to the active drug in the EpiPen®.

95. Mylan also used other strategies to combat competition from Auvi-Q®. When Auvi-Q® was released in 2013, Mylan's CEO, Heather Bresch,

was quoted stating that "EpiPen has been tried and true for 25 years…. It's not easily confused with a Blackberry or your phone in your purse or your backpack."[51] Mylan's fearmongering to doctors, patients, parents, and caregivers was that Auvi-Q® would be mistaken for some other technology device and not carried when needed to treat an anaphylactic episode.

96. Mylan also made misleading statements to physicians regarding Auvi-Q®'s exclusion from the marketplace. Mylan distributed materials to physicians touting that the EpiPen® is the "preferred brand" for major health plans covering 95 million patients. An image of these materials is below:

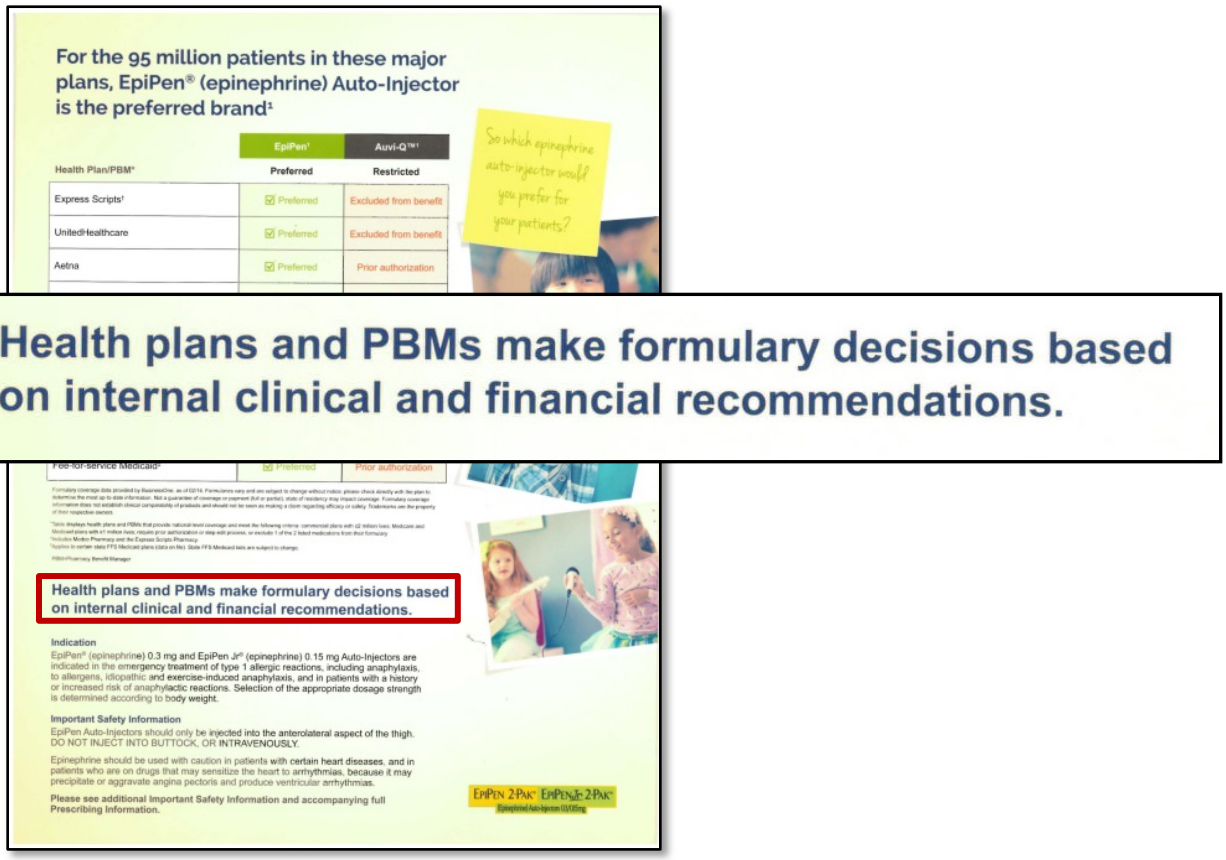
[51] N.Y. Times, Brothers Develop New Device to Halt Allergy Attacks.



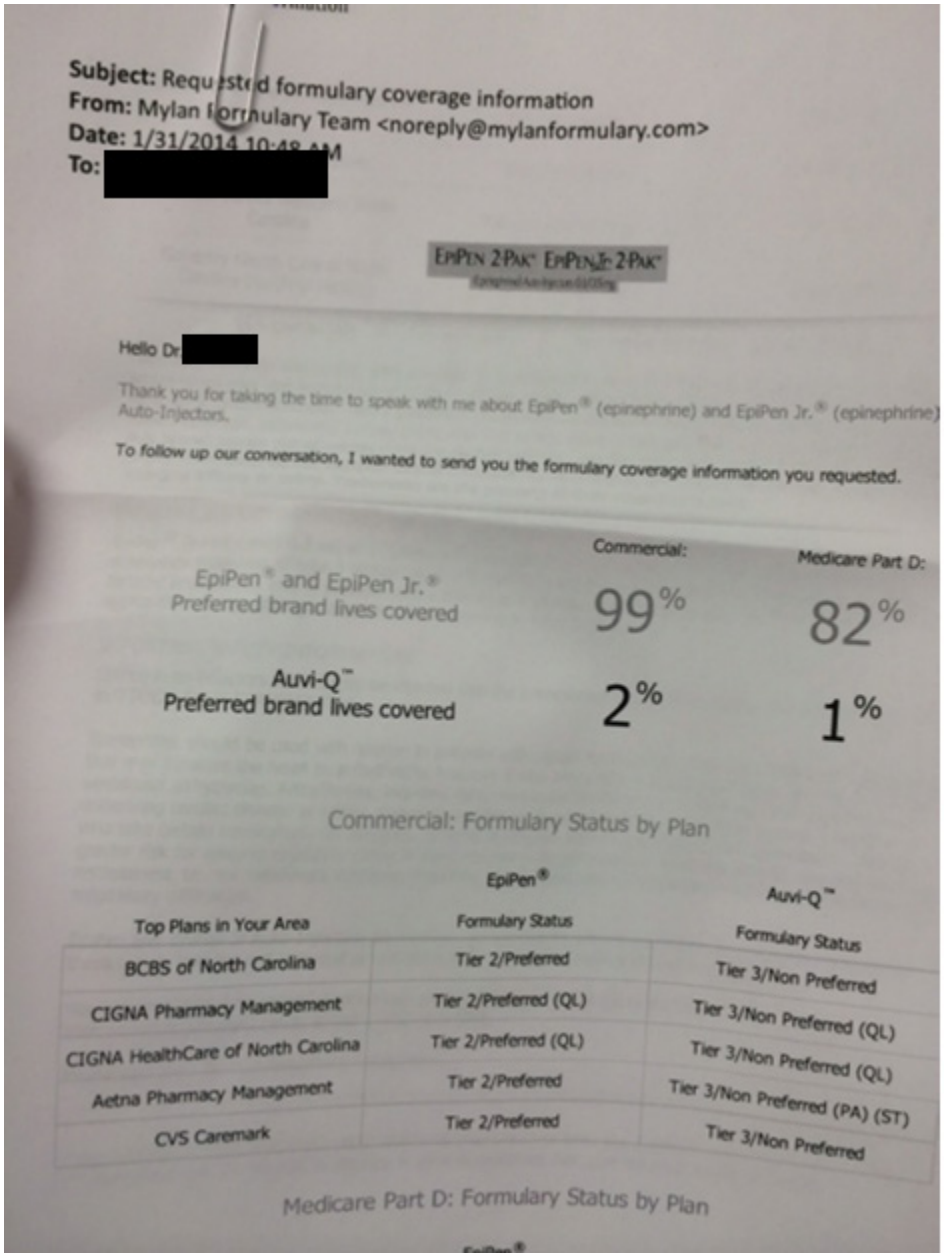
97. Through its anticompetitive conduct, Mylan itself created Auvi-Q®'s status of being "Excluded from Benefit," "Not Covered," "Non-Formulary," Step-edit,"[52] or "Prior Authorization" with these plans. Mylan paid formularies to exclude Auvi-Q® from coverage, but then marketed to physicians that Auvi-Q® was not covered by formularies and suggested that the decision to exclude

[52] "Step-edit" means that another drug must be tried first prior to the listed drug being covered.

Auvi-Q® from formulary was based on clinical recommendations, rather than on Mylan's huge, conditional rebate offers. Images of the flyer are below:



98. Mylan disseminated other misleading materials showcasing the effects of its exclusionary conditional rebates. In January 2014, just after all of Mylan's anticompetitive rebates went into effect blocking Auvi-Q® from some of the largest third-party payors, Mylan sent physicians marketing materials stating that Mylan was the "Preferred" EAI device for 99% of patients, while Auvi-Q® was "Preferred" for only 2%:



Subject: Requested formulary coverage information
From: Mylan Formulary Team <noreply@mylanformulary.com>
Date: 1/31/2014 10:48 AM
To: [redacted]

EpiPen 2-Pak® EpiPen Jr. 2-Pak®

Hello Dr [redacted]

Thank you for taking the time to speak with me about EpiPen® (epinephrine) and EpiPen Jr.® (epinephrine) Auto-Injectors.

To follow up our conversation, I wanted to send you the formulary coverage information you requested.

	Commercial:	Medicare Part D:
EpiPen® and EpiPen Jr.® Preferred brand lives covered	99%	82%
Auvi-Q™ Preferred brand lives covered	2%	1%

Commercial: Formulary Status by Plan

Top Plans in Your Area	EpiPen® Formulary Status	Auvi-Q™ Formulary Status
BCBS of North Carolina	Tier 2/Preferred	Tier 3/Non Preferred
CIGNA Pharmacy Management	Tier 2/Preferred (QL)	Tier 3/Non Preferred (QL)
CIGNA HealthCare of North Carolina	Tier 2/Preferred (QL)	Tier 3/Non Preferred (QL)
Aetna Pharmacy Management	Tier 2/Preferred	Tier 3/Non Preferred (PA) (ST)
CVS Caremark	Tier 2/Preferred	Tier 3/Non Preferred

Medicare Part D: Formulary Status by Plan

99. These marketing materials compounded the "spillover" effects from Mylan's blocking of Auvi-Q® from the market. Mylan did not only block Auvi-Q® from the market with its anti-competitive conditional discounts. Mylan then proactively touted the fact that Auvi-Q® was blocked from the market, ensuring

that physicians would think that the EpiPen® was the only realistic choice for their patients.

100. Despite Mylan's efforts to spread negative coverage about Auvi-Q®, Sanofi spoke to many physicians who preferred Auvi-Q® to the EpiPen®, but were concerned that their patients did not have access to Auvi-Q® because it was not covered by their insurance. Many physicians even wrote articles or letters to payors in support of Auvi-Q® to try to help get it covered.

K. Mylan's Conduct Harmed Sanofi

101. Sanofi lost significant sales as a result of Mylan's anti-competitive conduct. As detailed above, Mylan's conditional rebates blocked Sanofi from up to 50% of the EAI drug device market nationally, and in some states, more than 50% of the market.

102. Significantly, the absolute level of foreclosure does not even address the substantial spillover effects to Auvi-Q® from Mylan's efforts to limit the market. The actual effect of the conditional rebates on Auvi-Q®'s position in the marketplace was even greater than the absolute portion of the market from which Auvi-Q® is foreclosed due to "spillover" effects.

103. Many doctors who know that a majority of their patients have health insurance coverage with formularies that exclude Auvi-Q® will continue to prescribe EpiPen®. Most doctors are unable to take the extra time to inquire into

which health care plan covers each patient, and whether Auvi-Q® is available on its formulary, if the physician knows that the EpiPen® will be available for all of his or her patients. In addition, for patients who may have access to Auvi-Q® through formularies only if they receive prior authorization from a physician, many physicians do not have the time to take the necessary extra steps to authorize patients for Auvi-Q® if the EpiPen® is available without authorization, even if the physician believes that Auvi-Q® is a superior EAI drug device.

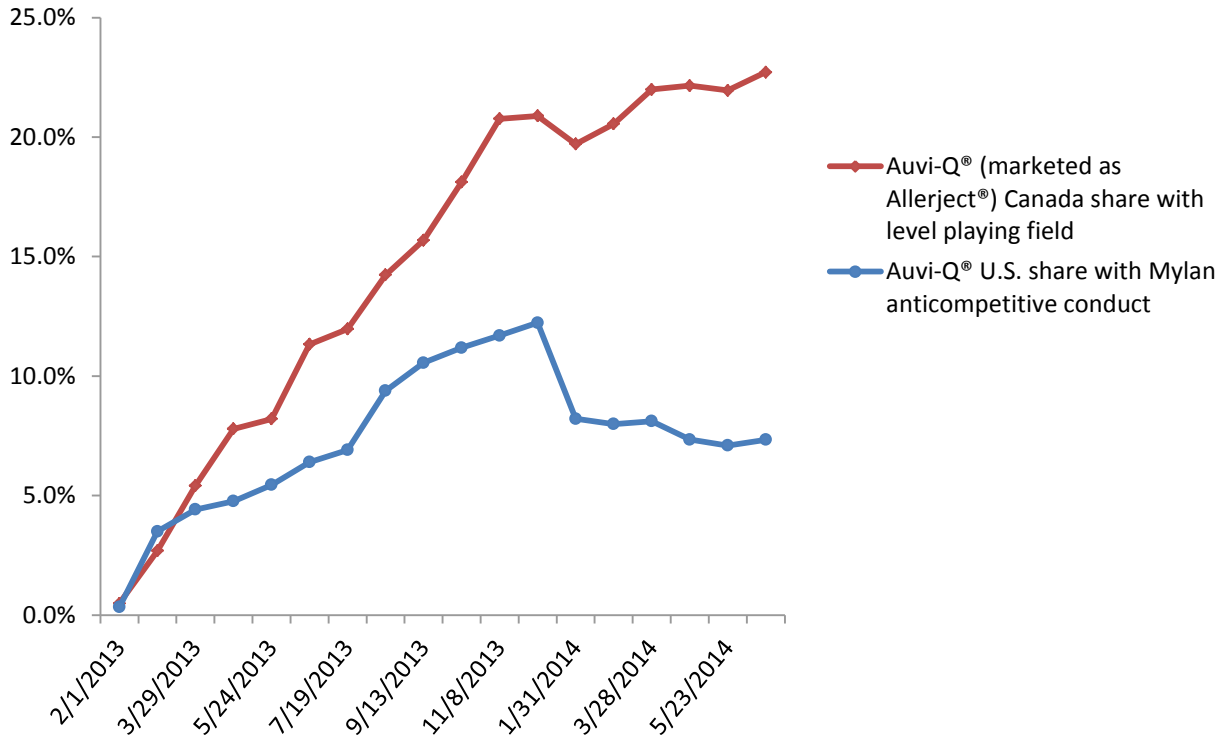
104. Sanofi's losses are shown by, among other measures, its lost Auvi-Q® market share after Mylan began offering its extraordinary, conditional rebates. Auvi-Q®'s actual market shares tracked its projected market shares through the first six months after Auvi-Q®'s launch in 2013, and Auvi-Q®'s share of the market was poised to continue to grow. After Mylan began its conditional rebates, Auvi-Q®'s market share fell dramatically. By the end of 2013 and into 2014, Auvi-Q®'s market share was approximately half of its projected market share. By April 2014, Auvi-Q®'s national market share had slid from a maximum of 11% in mid-2013 to only 6%, while its market share in 2014 had been projected by Sanofi to exceed 20%. By October 2015, Auvi-Q®'s national market share was less than half of what Sanofi had projected by that time.

105. Moreover, for third-party payors that listed Auvi-Q® at the same coverage tier as the EpiPen®, Auvi-Q® met or exceeded its forecasts, reaching as

high as 20-25% share for those payors by the end of 2013, and exceeding 30% share for those payors in 2015.

106. Auvi-Q®'s much stronger performance in Canada versus the United States also reveals that Mylan injured Sanofi. In Canada, Auvi-Q® (there known as Allerject®) did not face the same type of anti-competitive conduct from the EpiPen®, although the EpiPen® similarly dominated the Canadian EAI drug device market before Sanofi launched the Allerject® there. Canadian provincial authorities control drug formularies, and the Allerject® was treated at parity with the EpiPen®, and the two devices were equally available for physicians to prescribe to consumers. After its launch, Allerject® exceeded its projections, growing to 21% market share by the end of 2013, its first year on the market. In 2014 and 2015, Allerject® had continued to gain market share, reaching 25% market share by the end of 2014, and peaking at 32% market share in 2015.

107. The growth of Allerject® in Canada, and physician and patient enthusiasm for the device in Canada, illustrates Auvi-Q®'s sales potential where an entrenched competitor is not able to manipulate the market and tip the scales in its own favor. A comparison of Auvi-Q®'s market share in the U.S. and Allerject®'s market share in Canada is below:



108. Sanofi also incurred significantly higher costs as a result of Mylan's conduct, because of much higher rebates on sales of Auvi-Q®, and on rebates of one of Sanofi's leading drugs. To try (and at least in one case) succeed to regain formulary access for Auvi-Q® on the formularies of some of the largest third-party payors, Sanofi was forced to offer substantial rebates on both Auvi-Q® and on one of its leading drugs. These rebates were especially harmful to a new entrant into a market with an entrenched monopolist, which incurred other major expenses related to marketing its new product and educating key stakeholders.

109. Sanofi also incurred higher costs than Mylan because Mylan's conduct caused Auvi-Q® to be listed at a "non-preferred" tier as compared with the

EpiPen®. Before Sanofi launched Auvi-Q®, market research revealed that Mylan had not offered a $0 co-pay card, or had offered such an incentive in rare circumstances. Only after Auvi-Q® launched did Mylan decide to begin offering consumers $0 co-pay coupons for the EpiPen®. Sanofi also offered $0 co-pay coupons for Auvi-Q®. But, because of Mylan's rebate offers to third-party payors, most of Auvi-Q®'s coverage – even where it was on a drug formulary with the EpiPen® – was at less preferential T3 level versus T2 level. This typically meant the co-pay for an EpiPen® was $25 and a co-pay for Auvi-Q® was $50-$75. As a result, Sanofi was being forced to absorb two to three times the cost Mylan was absorbing to level the playing field and ensure patients paid a $0 co-pay. Thus, Mylan drove up Sanofi's costs to cover patients' co-pays.

110. Subsequently, in October 2015, Sanofi undertook a voluntary recall of Auvi-Q® following reports of manufacturing issues affecting some devices.[53] Mylan's conduct contributed to Sanofi forgoing its investment in Auvi-Q® and

[53] Sanofi Press Release, "Sanofi U.S., UPDATED: Sanofi US Issues Voluntary Nationwide Recall of All Auvi-Q® Due to Potential Inaccurate Dosage Delivery" (Oct. 30, 2016), http://www.multivu.com/players/English/7673951-sanofi-auto-injector-recall/. Recalls are not uncommon for pharmaceuticals like EAI drug devices, where manufacturers and patients demand flawless products. Mylan also undertook a recall of EpiPens® in March-April 2017. *See* Mylan Press Release, "Mylan Provides Update on Meridian Medical Technologies', a Pfizer Company, Expanded Voluntary Worldwide Recall of EpiPen® Auto-Injector" (Mar. 31, 2017) http://newsroom.mylan.com/2017-03-31-Mylan-Provides-Update-on-Meridian-Medical-Technologies-a-Pfizer-Company-Expanded-Voluntary-Worldwide-Recall-of-EpiPen-R-Auto-Injector.

returning the rights to the drug to kaléo, inc. in February 2016, rather than re-launching Auvi-Q®.[54]

L. Mylan's Conduct Harmed U.S. Consumers

111. Mylan's conduct also hurt consumers in the United States. Mylan deprived consumers of choice when it comes to the treatment of life-threatening allergies.

112. As noted above, when Auvi-Q® was launched physicians welcomed the new device as bringing innovation to a marketplace that had seen little improvement in decades, and promised to increase people's usage of EAI drug devices.

113. Mylan's anticompetitive conduct prevented patients and caregivers from accessing Auvi-Q®, unless they were able to pay the full out of pocket cost. This amounted to hundreds of dollars necessary to purchase the device—and in most cases to purchase multiple devices per patient, to keep at home, at school or the office, and to carry elsewhere—above the thousands of dollars that those patients and caregivers already pay for health insurance coverage, which they would expect to cover a drug such as Auvi-Q®. Doctors, even those who recognize the benefits of Auvi-Q® and would have preferred to prescribe Auvi-Q® rather than

[54] Sanofi Press Release, "Sanofi US to Return Auvi-Q® (epinephrine injection, USP) Rights to kaléo" (Feb. 23, 2016), http://www.news.sanofi.us/2016-02-23-Sanofi-US-to-Return-Auvi-Q-epinephrine-injection-USP-Rights-to-kal-o.

the EpiPen®, found themselves in the difficult position of asking patients to pay the hundreds of extra dollars for Auvi-Q® or prescribing EpiPen® knowing that Auvi-Q® may be a superior device for certain patients who are unlikely to carry the EpiPen® with them at all times, but may be more likely to carry Auvi-Q®. That is why out-of-pocket sales of EAI drug devices are a tiny fraction of the market.

114. Further, patients typically cannot choose a new third-party payor if they are dissatisfied with the formulary coverage available through their employer-sponsored health plan. Therefore, Mylan was able to block access to Auvi-Q® by nearly 50% of patients—and in some states, more than 50% of patients—by offering its large conditional rebates to the largest commercial payors covering the most lives. If patients preferred Auvi-Q® to the EpiPen®—and evidence from Canada and from payors that offered Auvi-Q® on equal terms with the EpiPen® shows that many did—but were enrolled with a third-party payor that excluded Auvi-Q®, they still typically could not choose to use an alternative third-party payor that would cover Auvi-Q®. Mylan's conduct took the ability to choose which EAI drug device to use out of patients' and physicians' hands by acting to exclude Auvi-Q® from coverage for most patients.

115. Finally, Mylan's conduct suppressed innovation. U.S. consumers were prevented from gaining access to a new EAI drug device that represented the first truly new and innovative competition to the EpiPen®. For example, Canadian

consumers, who had much greater access to Allerject® because the playing field was level with the EpiPen®, chose Allerject® for one-in-three prescriptions by 2015. U.S. consumers never had that opportunity.

EAI DRUG DEVICES IN THE UNITED STATES IS A RELEVANT MARKET

116. EAI drug devices are a relevant product market.

117. The relevant geographic market is the United States.

118. EAI drug devices are sold throughout the United States. People who suffer from anaphylaxis live across the country. Pricing for EAI drug devices is done on a national basis.

119. The use of epinephrine is the recognized first-line treatment for anaphylaxis, and EAI drug devices are the standard method for patients to have access to epinephrine at all times in case of emergency. The medical community unequivocally recommends that an individual carry an EAI drug device at all times in case of an anaphylactic episode. Doctors recommend the administration of epinephrine, followed by contacting medical help, in cases of anaphylaxis. No drug is interchangeable with epinephrine to treat anaphylaxis. No drug device is interchangeable with an EAI to treat an anaphylactic episode. Put simply, there is no alternative or substitute for an EAI drug device.

120. Mylan has admitted that EAI drug devices are a relevant product market and that the EpiPen® dominates that market. For example, on April 26,

2012, John Sheehan, the CFO of Mylan, has stated (in reference to Mylan's EpiPen®) that "***we are the market for anaphylactic shock with over 98% market share***."[55]

121. Sanofi was a competitor in the relevant market because from January 2013 thru October 2015 they marketed and distributed an EAI drug device. As explained above, Mylan has engaged in anticompetitive practices aimed at excluding Sanofi from distributing its new EAI drug device, Auvi-Q®. The CEO of Mylan, Heather Bresch, has recognized that because so few people at risk for anaphylactic episodes use EpiPens®, there is room in the market for a competitor.[56] However, Mylan has ensured its position as the eponymous purveyor of EAI drug devices by engaging in anticompetitive conduct to ensure its monopoly. By effectively blocking potential channels of sale and distribution, Mylan is maintaining its monopoly position at the expense of a competitive market.

MONOPOLY POWER

122. The EAI drug device market in the United States has been dominated by the EpiPen®.

123. Mylan has admitted in numerous public statements that it controls the EAI drug device market with close to a 100% market share. For example, in

[55] Transcript, Mylan Inc., Earnings Call (April 26, 2012).

[56] N.Y. Times, Tiny Lifesaver for a Growing Worry.

referencing the EpiPen®, Mylan's CFO, John Sheehan, proclaimed on April 26, 2012 that "***we are the market for anaphylactic shock with over 98% market share***".[57] Similarly, on August 1, 2013, Mylan touted to investors that the EpiPen® had a "***93.3% market share***".[58]

124. Beyond Mylan's EpiPen® market share, Mylan's monopoly power is evidenced by its ability to take price increases without any loss in sales.

125. Since 2007, the EpiPen®'s price has increased by 500%. A chart of Mylan's price increases for the EpiPen® is below:[59]

[57] Transcript, Mylan Inc., Earnings Call (April 26, 2012).

[58] Presentation, Mylan Inc., Mylan Investor Day: Seeing is Believing, (Aug. 1, 2013).

[59] John C. Ogg, *Concerns Persist on Mylan EpiPen Price Gouging — or Do They?*, 24/7 WALL ST. (Aug. 24, 2016), http://247wallst.com/healthcare-business/2016/08/24/more-concerns-persist-on-mylan-epipen-price-gouging-or-do-they/.

Despite Mylan's price increases, the EpiPen®'s market share has remained stable at extraordinarily high levels.

BARRIERS TO ENTRY

126. The EAI drug device market in the United States is characterized by difficult entry conditions and durable barriers to entry that protect and fortify Mylan's monopoly power.

127. Since 2005, three other EAI drug devices, Twinject®, Adrenaclick™, and a generic EpiPen® from Teva Pharmaceuticals, have attempted to enter the EAI market, with limited if any, success. Twinject® has been discontinued and Adrenaclick™ had been marginalized until the widespread outcry against Mylan's EpiPen® pricing. The Teva Pharmaceuticals device continues to face delays and

regulatory hurdles associated with gaining FDA approval before it can enter the market later this year, at the earliest.

128. Because EAI drug devices must be prescribed by a medical professional, there is a lengthy Food and Drug Administration (FDA) approval process that any potential new entrants must undergo to enter the market and to show that the epinephrine used in the device is bioequivalent to the EpiPen®. Demonstrating bioequivalence to EpiPen® is not required for FDA approval, but it is a crucial hurdle for a new entrant to convince EpiPen® customers to switch to a new EAI drug device.

129. Furthermore, prescriptions for EAI drug devices are infrequently filled, usually only once per year unless there is a refill need due to an anaphylactic event. Additionally, current users of EAI drug devices may be wary of a new product because the EpiPen® is well-known and most caregivers and physicians are trained on the EpiPen®, but may not be trained on a new product.

130. Mylan recognized that the nature of EAI drug devices naturally led to slow "uptake" of competitors to the EpiPen®. Mylan's CFO, John Sheehan, stated in Mylan's March 4, 2014 earnings call that:

> We believe that ***given the brand equity, given the fact that you only renew a script for EpiPen one time per year, not every single month, given the importance of the product for it being used in a life-saving situation,*** we don't believe that even in a situation where a competitor was to receive a generic approval that the uptake would be anything near let's say a typical oral solid dose product generic uptake. ***We would see the uptake being slow***

> ***and ramp up slowly over time. And I think you'd measure that time over a period of years as opposed to a period of months.***

Although Mr. Sheehan was discussing consumers' switch to a generic EpiPen®, these market factors that protect the EpiPen® from a generic also help protect the EpiPen® from a new branded competitor such as Auvi-Q®.

131. There are additional, artificial barriers to entry erected to protect the EpiPen®. The holders of patents protecting the EpiPen® have at least twice filed patent infringement lawsuits against potential new entrants, claiming that they infringe patents protecting the EpiPen® through 2025.

132. In the case of Auvi-Q®, the patent allegedly infringed by Auvi-Q® relates to a mechanism to cover the needle after use—despite the fact that Auvi-Q®'s needle retracts, and plainly uses an entirely different mechanism to prevent accidental sticking with its needle. Mylan and Pfizer announced that the EpiPen®'s patent-holders settled the Auvi-Q® case, allowing Auvi-Q® to enter the market after November 15, 2012.[60] Auvi-Q® was launched in 2013, spurring Mylan to engage in the anti-competitive conduct that is the subject of this Complaint to block the competitive threat posed by Auvi-Q®.

133. EpiPen®'s patent-holders also brought a patent infringement lawsuit, which they then settled, against Teva for the generic EpiPen®. That settlement

[60] Mylan Press Release, "Mylan Inc., Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement" (Feb. 16, 2012), http://investor.mylan.com/releasedetail.cfm?releaseid=649300.

allowed Teva to enter the market nearly 10 years prior to the expiry of the EpiPen®-related patents. Despite the settlement allowing Teva to bring a generic EpiPen® to market, Mylan has noted that high regulatory hurdles continue to exist for the generic to be listed as an AB-rated substitutable EAI drug device. Mylan also filed a citizen petition requesting that the FDA decline to approve Teva's generic EpiPen®. Indeed, Heather Bresch, Mylan's CEO, has "been pretty vocal about the fact that [she] think[s] ***the bar to get an AB-rated substitutable product is very high***." Teva has struggled with the regulatory hurdles, and has announced that it aims to enter the market with a generic version of EpiPen® in late 2017 or early 2018.

134. Mylan's anticompetitive conduct reinforced and exacerbated these barriers by making it impossible for Auvi-Q® to enter the market and effectively compete with the EpiPen®.

FIRST CLAIM FOR RELIEF: MYLAN'S EXCLUSIVE DEALING IN THE U.S. EAI DRUG DEVICE MARKET IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

135. Sanofi incorporates the material fact allegations of paragraphs 1-134.

136. During the relevant period, Mylan had monopoly power in the U.S. EAI drug device market. Mylan unlawfully maintained its monopoly power through anticompetitive acts of exclusive dealing. Specifically, Mylan excluded Auvi-Q® from the market by conditioning its rebates—leveraged across all of its

EpiPen® volume—on drug formulary exclusivity in order to foreclose Auvi-Q® from a substantial share of the relevant market. Mylan acted with the specific intent to illegally maintain its monopoly over the sale of EAI drug devices. Mylan's conduct violated Section 2 of the Sherman Act, 15 U.S.C. § 2.

137. Mylan's unlawful conduct directly and proximately caused injury to interstate commerce and to Sanofi's business and property. Specifically, Sanofi lost hundreds of millions of dollars in sales from within the $1 billion-plus U.S. EAI drug device market that would have taken place but for Mylan's behavior. Sanofi also incurred significantly higher costs in the form of rebates on Auvi-Q® and, in at least one case, on a leading Sanofi drug product, in order to get key third-party payors just to cover Auvi-Q® along with the EpiPen®. Sanofi incurred additional increased costs with respect to the higher co-pays that it paid to match Mylan's offers of $0 co-pay coupons for patients as a result of Sanofi's disadvantaged placement on third-party payor drug formularies because of Mylan's conditional rebates. Further, Sanofi ultimately decided to return the marketing rights for Auvi-Q® back to the creators of the device in part because of the artificial barriers to entry Mylan's conduct erected. Sanofi's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Mylan's anticompetitive conduct in violation of Section 2 of the Sherman Act.

SECOND CLAIM FOR RELIEF: MYLAN'S DECEPTIVE CONDUCT TO FURTHER ITS MONOPOLIZATION OF THE U.S. EAI DRUG DEVICE MARKET IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

138. Sanofi incorporates the material fact allegations of paragraphs 1-137.

139. During the relevant period, Mylan had monopoly power in the U.S. EAI drug device market. Mylan unlawfully maintained its monopoly power through deceptive conduct aimed at spreading disinformation about the safety and efficacy of Auvi-Q®. Specifically, Mylan circulated marketing materials to physicians and key thought leaders falsely suggesting that Auvi-Q® was not bioequivalent to the EpiPen®, and that formularies had listed Auvi-Q® as NC or PA based on clinical recommendations. Mylan acted with the specific intent to illegally maintain its monopoly over the sale of EAI drug devices. Mylan's conduct violated Section 2 of the Sherman Act, 15 U.S.C. § 2.

140. Mylan's unlawful conduct directly and proximately caused injury to interstate commerce and to Sanofi's business and property. Specifically, Sanofi lost hundreds of millions of dollars in sales from within the $1 billion-plus U.S. EAI drug device market that would have taken place but for Mylan's behavior. Sanofi also incurred significantly higher costs in the form of rebates on Auvi-Q® and, in at least one case, on a leading Sanofi drug product, in order to get key third-party payors just to cover Auvi-Q® along with the EpiPen®. Sanofi also incurred increased marketing costs to correct Mylan's misleading statements with

physicians and key thought leaders. Sanofi incurred additional increased costs with respect to the higher co-pays that it paid to match Mylan's offers of $0 co-pay coupons for patients as a result of Sanofi's disadvantaged placement on third-party payor drug formularies because of Mylan's conditional rebates. Further, Sanofi ultimately decided to return the marketing rights for Auvi-Q® back to the creators of the device in part because of the artificial barriers to entry Mylan's conduct erected. Sanofi's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Mylan's anticompetitive conduct in violation of Section 2 of the Sherman Act.

THIRD CLAIM FOR RELIEF: MYLAN'S OVERALL SCHEME TO MONOPOLIZE THE U.S. EAI DRUG DEVICE MARKET IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

141. Sanofi incorporates the material fact allegations of paragraphs 1-140.

142. During the relevant period, Mylan had monopoly power in the U.S. EAI drug device market. In addition to Mylan's unlawful exclusive dealing and deceptive marketing, Mylan engaged in other anticompetitive conduct designed to maintain its monopoly power in the relevant market. Mylan required schools to agree to exclusively stock EpiPens® to participate in Mylan's discounted EpiPen® program. Mylan sharply raised the price of the EpiPen®, allowing it to offer larger rebates to payors to exclude Auvi-Q®. And Mylan touted the "preferred" formulary positions that it gained even when it didn't exclude Auvi-Q® entirely,

and raised consumers' co-pay costs and Sanofi's costs for co-pay coupons. Mylan acted with the specific intent to illegally maintain its monopoly over the sale of EAI drug devices. Mylan's conduct violated Section 2 of the Sherman Act, 15 U.S.C. § 2.

143. Mylan's unlawful conduct directly and proximately caused injury to interstate commerce and to Sanofi's business and property. Specifically, Sanofi lost hundreds of millions of dollars in sales from within the $1 billion-plus U.S. EAI drug device market that would have taken place but for Mylan's behavior. Sanofi also incurred significantly higher costs in the form of rebates on Auvi-Q® and, in at least one case, on a leading Sanofi drug product, in order to get key third-party payors just to cover Auvi-Q® along with the EpiPen®. Sanofi incurred additional increased costs with respect to the higher co-pays that it paid to match Mylan's offers of $0 co-pay coupons for patients as a result of Sanofi's disadvantaged placement on third-party payor drug formularies because of Mylan's conditional rebates. Sanofi ultimately decided to return the marketing rights for Auvi-Q® back to the creators of the device in part because of the artificial barriers to entry Mylan's conduct erected. Sanofi's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Mylan's anticompetitive conduct in violation of Section 2 of the Sherman Act.

RELIEF REQUESTED

144. Sanofi requests that the Court find that the conduct of Mylan as specified in this Complaint violates Section 2 of the Sherman Act.

145. Sanofi requests that the Court require Mylan to pay Sanofi treble the amount of damages Sanofi has suffered as a result of Mylan's illegal conduct.

146. Sanofi further requests its costs for bringing this action, including reasonable attorneys' fees.

147. Sanofi also requests such other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands trial by jury.

DATED: April 24, 2017

Respectfully Submitted,

_/s/ Diane Sullivan____

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