UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS INC., FWK HOLDINGS LLC, and CÉSAR CASTILLO, LLC, individually and on behalf of all those similarly situated, Plaintiffs, v. MYLAN, N.V., MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., PFIZER, INC., KING PHARMACEUTICALS, INC., and MERIDIAN MEDICAL TECHNOLOGIES, INC., Defendants.	Civil Action No. 2:20-cv-02065-DDC-TJJ CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

CONSOLIDATED FOURTH AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

I. NATURE OF THE CASE 1

II. JURISDICTION AND VENUE 3

III. THE PARTIES 4

IV. LEGAL AND REGULATORY INDUSTRY BACKGROUND 9

A. The Regulatory Structure for the Approval of Drugs and Substitution of Generics for Brand Name Drugs 9

B. The Hatch-Waxman Amendments Advanced the Goal of Providing Access to Generic Drugs 10

C. ANDA Patent Certifications Provide Incentives to Generic Manufacturers to Challenge Patents 12

D. Generic Competition Serves the Public Interest 14

E. Drug Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms 17

F. Genuine Citizen Petitions to the FDA Serve a Public Good; Fraudulent Petitions Delay Generic Competition 22

G. EAIs and FDA Approval 25

V. STATEMENT OF FACTS 25

A. Epinephrine Auto-Injectors 25

B. Defendants Unlawfully Delayed Generic Competition 31

1. Teva Litigation 33

2. Intellijject/Auvi-Q Litigation 40

3. Sandoz Litigation 42

4. Mylan's Meritless Citizen Petition 42

5. The Availability of Teva's AB-Rated Generic EpiPen Was Substantially Delayed as a Direct Result of Defendants' Misconduct 45

C. Defendants Shamelessly Exploited Their Market Dominance by Charging Outrageous and Supra-Competitive Prices for EpiPens 46

VI. DEFENDANTS'ACTIONS IMPACT INTERSTATE TRADE AND COMMERCE 50

VII. MARKET POWER AND DEFINITION 51

VIII. ANTITRUST IMPACT AND DAMAGES TO THE CLASS 55

IX. TOLLING OF STATUTES OF LIMITATION 57

X. CLASS ACTION ALLEGATIONS 60

XI. CAUSES OF ACTION 62

XII. PRAYER FOR RELIEF 66
XIII. JURY DEMAND 66
XIV. DESIGNATION OF PLACE OF TRIAL 66

1. Plaintiffs KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("KPH"), FWK Holdings, LLC ("FWK"), and César Castillo, LLC ("Castillo") (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, hereby bring this Consolidated Fourth Amended Class Action Complaint against defendants Mylan N.V; Mylan Pharmaceuticals Inc.; Mylan Specialty L.P. (collectively, "Mylan"); Pfizer, Inc., King Pharmaceuticals, Inc. ("King") and Meridian Medical Technologies, Inc. ("Meridian")[1] (collectively, "Defendants"). Plaintiffs make the allegations herein based on personal knowledge relating to themselves and upon investigation and information and belief as to all other matters.

I. NATURE OF THE CASE

2. This civil antitrust action concerns Defendants' anticompetitive and unlawful conspiracy and agreements in restraint of trade to substantially delay the onset of generic competition for the EpiPen[2]—a disposable, prefilled, FDA-approved epinephrine auto injector ("EAI").

3. Anaphylaxis is a serious and potentially life-threatening allergic reaction if not promptly and appropriately treated. The drug epinephrine (commonly referred to as adrenaline) is the only appropriate first-line treatment for anaphylaxis. EAIs are FDA-approved devices used to self-deliver a controlled dose of epinephrine.

4. For more than two decades prior to 2018, the EpiPen was the number-one prescribed EAI in the United States (oftentimes with a market share exceeding 90%). Between

[1] Pfizer, Inc., King Pharmaceuticals, Inc., and Meridian Medical Technologies, Inc., are collectively referred to herein as "Pfizer" or the "Pfizer Defendants."

[2] The term "EpiPen", as used herein, refers to EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, EpiPen Jr. 2-Pak®, My EpiPen®, LIFE HAPPENS®, EpiPen4Schools®, Never-See-Needle®, and Be Prepared®.

1996 and July 2013, Meridian (now a subsidiary of Pfizer) owned the EpiPen NDA and related patents and manufactured all EpiPens sold in the United States. In 1997, Meridian sold the exclusive right to distribute EpiPens in the United States to Dey LP, which was acquired by Mylan Pharmaceuticals, Inc. in 2007, and subsequently renamed Mylan Specialty, L.P. Meridian assigned the EpiPen NDA to related patents to Mylan in July 2013 and December 2020, respectively.

5. A 2010 Supply Agreement between Meridian and Mylan established a Joint Commercial Committee designed to streamline distribution of EpiPen products. Pursuant to the Supply Agreement, Meridian was required to supply Mylan with EpiPens as requested by Mylan and compensated based on the number of EpiPens provided to Mylan.

6. In furtherance of their scheme to maintain monopoly power over the EAI market by artificially delaying entry of an AB-rated generic EpiPen, on April 26, 2012, Defendants entered into a series of unlawful and anticompetitive agreements with generic drug manufacturer, Teva Pharmaceuticals USA, Inc. ("Teva"). Pursuant to those agreements, Defendants and Teva agreed to delay entry of Teva's AB-rated generic EpiPen until June 22, 2015 (subject to FDA approval) and settle patent litigation related to Teva's ANDA to manufacture and market an AB-rated generic EpiPen (after the conclusion of a bench trial in that matter but before a verdict was entered). In exchange, Teva and Mylan agreed to delay entry of Mylan's generic version of Nuvigil—a blockbuster drug owned by Teva—until June 1, 2016, and to settle patent litigation related to Mylan's ANDA to market a generic version of Nuvigil. Such market allocation agreements amongst horizontal competitors constitute a per se violation of federal antitrust laws.

7. Absent the illegal agreements, generic entry of an AB-rated generic EpiPen would have commenced in or around March 2014, and Plaintiffs and other direct purchasers of EpiPens

would have been able to pay significantly lower prices than they were forced to pay because of Defendants' unlawful and anticompetitive conduct to delay generic entry.

8. Defendants were shameless in profiting off EpiPen's exclusivity. Between 2007 and 2016, the list price for two EpiPens increased more than sixfold, from $100 in 2007 to $608 in 2016.[3] The large price increases were not attributable to increased manufacturing costs or any epinephrine supply shortage.

9. Plaintiffs and Class Members seek overcharge damages arising from Defendants' unlawful, anticompetitive, and exclusionary conduct, plus treble damages for overcharges they paid to Mylan and/or Teva.

II. JURISDICTION AND VENUE

10. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks the recovery of treble damages, costs of suit, and reasonable attorneys' fees for the injuries that Plaintiffs and members of the Class (defined below) sustained as a result of Defendants' anticompetitive conduct. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15.

11. Venue is proper in this District pursuant to 15 U.S.C. §§ 15, 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of Defendants' activity that affected the interstate trade and commerce discussed below has been carried out in this District.

[3] Mark Zaleski, *Mylan Overcharged Medicaid for EpiPen for Years, Despite Warnings*, STAT (Oct. 5, 2009), https://www.statnews.com/pharmalot/2016/10/05/mylan-overcharged-medicaid-epipen/.

12. During the Class Period, Defendants sold and shipped EpiPens in a continuous and uninterrupted flow of interstate commerce, which included sales in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

13. This Court has *in personam* jurisdiction over Defendants because they, either directly or through the ownership and/or control of their subsidiaries, inter alia: (a) transacted business throughout the United States, including in this District; (b) had and maintained substantial aggregate contacts with the United States as a whole, including in this District; or (c) were engaged in an illegal conspiracy that was directed at, and had a direct, substantial, reasonably foreseeable, and intended effect of causing injury to the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this District. Defendants also conduct business throughout the United States, including in this District, and have purposefully availed themselves of the laws of the United States.

III. THE PARTIES

A. PLAINTIFFS

14. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc.

15. KPH is the assignee of McKesson Corporation, which, through its direct purchases of EpiPen from Mylan during the Class Period, was the first innocent purchaser within the chain of EpiPen purchasers. As a result of Defendants' alleged anticompetitive conduct, McKesson paid supra-competitive prices for its EpiPen purchases, and thus was the first direct victim within the

chain of commerce to be injured by the illegal conduct of Defendants alleged herein. KPH pursues relief in this action as McKesson's assignee.

16. The December 12, 2018 Assignment Agreement states that KPH purchases from McKesson EpiPen, described as "a brand-name drug manufactured and/or marketed by Mylan Specialty L.P. ('Manufacturer Supplier')." Pursuant to the Assignment Agreement, McKesson assigned and transferred to KPH "one hundred percent (100%) of all rights, title and interest in and to any antitrust cause of action it may have against Manufacturer/Supplier under the laws of the United States or of any state (a) so long as the gravamen of the cause of action is that the Manufacturer/Supplier unlawfully delayed or frustrated the introduction or sale of generic EpiPen and (b) only to the extent the cause of action arises from McKesson's purchase of EpiPen that were subsequently resold to KPH during the period from November 1, 2013 to present." Assignment Agreement ¶ E(1) (Dec. 12, 2018).

17. On August 31, 2020, KPH and McKesson executed an Addendum nunc pro tunc to clarify the scope of the Assignment Agreement. The Addendum notes that KPH purchases from McKesson EpiPen products, described as "a brand-name drug manufactured and/or marketed by Mylan Specialty L.P., Mylan N.V., Mylan Pharmaceuticals, Inc., Pfizer, Inc., King Pharmaceuticals Inc., and Meridian Medical Technologies Inc. ('Manufacturers/Suppliers')." Addendum to December 12, 2018 Agreement for Assignment of Claims ¶ A. Concerning the scope of the assignment, the Addendum provides:

> McKesson hereby conveys, assigns, and transfers to [KPH] one hundred percent (100%) of all rights, title and interest in and to any antitrust cause of action it may have against Manufacturers/Suppliers and co-conspirators under the laws of the United States or of any State, (a) so long as the cause(s) of action include that the Manufacturers/Suppliers unlawfully delayed or frustrated the introduction or sale of generic EpiPen and/or participated in conduct which violated the Sherman Act or Clayton

> Act; and (b) only to the extent the cause of action arises from purchases of EpiPen that were subsequently resold to [KPH] during the period from November 2, 2013 through the present.

18. In executing the Assignment Agreement, the intent of both KPH and McKesson was for McKesson to assign to KPH all antitrust claims McKesson had against the manufacturers and suppliers of EpiPens for unlawfully delaying entry of generic EpiPens in violation of the Sherman Act and/or Clayton Act arising from McKesson's purchases of EpiPens subsequently resold to KPH during the defined period.[4]

19. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois limited liability company with its principal place of business located in Glen Ellyn, Illinois.

20. FWK is the assignee of Frank W. Kerr. Co. ("Kerr") which, through its direct purchases of EpiPens from Mylan during the Class Period, was the first innocent purchaser within the chain of EpiPen purchasers. As a result of Defendants' alleged anticompetitive conduct, Kerr paid supra-competitive prices for its EpiPen purchases, and thus was the first direct victim within the chain of commerce to be injured by the illegal conduct of Defendants alleged herein. KPH pursues relief in this action as Kerr's assignee.

21. Plaintiff César Castillo, LLC ("Castillo") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business located at Rd. #1 Km. 21.1, PR-1, Guaynabo, Puerto Rico, 00971. During the Class Period (as defined below), Castillo

---

[4] This Court's July 26, 2021 Memorandum Opinion dismissed the Second Amended Class Action Complaint against Defendants without prejudice based on the holding that Plaintiff KPH did not allege facts sufficient to establish antitrust standing, but granted Plaintiff leave to file an amended complaint to cure the pleading deficiencies, recognizing the Supreme Court's instruction that "courts should afford plaintiff an opportunity to test its claim on the merits and should freely grant leave." Mem. Op. (ECF No. 113) at pp. 25-26 (punctuation and citation omitted).

purchased EpiPen and generic EpiPen directly from Defendants. As a result of Defendants' anticompetitive conduct, Castillo paid supra-competitive prices for its EpiPen and generic EpiPen purchases and Castillo was injured by the illegal conduct alleged herein. Castillo brings these claims as a direct purchaser and none of Castillo's claims are based on an assignment.

B. DEFENDANTS

22. Defendant Mylan N.V. was a Netherlands entity. Mylan N.V. was originally incorporated as a private limited liability company, New Moon B.V., in the Netherlands in 2014. On February 27, 2015, Mylan N.V. became a public limited liability company in the Netherlands through a corporate tax inversion, which it describes as an "acquisition of the EPD Business." Mylan N.V.'s corporate headquarters was located in Amsterdam, the Netherlands; its principal executive offices are located in Hatfield, Hertfordshire, England; and its group's global headquarters was located in Canonsburg, Pennsylvania. Mylan N.V. merged with the Upjohn division of Pfizer Inc. in 2020 to form Viatris Inc., which is a Delaware corporation headquartered in Canonsburg, Pennsylvania.

23. Defendant Mylan Pharmaceuticals Inc. is headquartered in Canonsburg, Pennsylvania and conducts extensive business nationwide. Mylan Pharmaceuticals Inc. is a wholly owned indirect subsidiary of Viatris Inc.

24. Defendant Mylan Specialty L.P. is a limited partnership with its principal office located in Morgantown, West Virginia. Mylan Specialty L.P.'s general partner is Dey, Inc., located in Canonsburg, Pennsylvania. Mylan Specialty, L.P. is a wholly owned indirect subsidiary of Mylan Pharmaceuticals Inc. Mylan Specialty L.P. was known as Dey Pharma until 2012, when it changed its name to align its operations under the Mylan brand.

25. Together, Mylan Specialty L.P. and Mylan Pharmaceuticals, Inc. are collectively referred to herein as "Mylan" and the "Mylan Defendants."

26. Defendant Pfizer, Inc. is a global pharmaceutical company with its global headquarters in New York, New York. Through its subsidiaries King Pharmaceuticals, Inc., and Meridian Medical Technologies, Inc., Pfizer supplies Mylan with 100% of its EpiPens sold in the United States.

27. Defendant King Pharmaceuticals, Inc., is headquartered in Bristol, Tennessee. King is a wholly owned subsidiary of Pfizer, Inc. King performs basic research and develops, manufactures, markets, and sells branded prescription pharmaceutical products and animal health products.

28. Defendant Meridian Medical Technologies, Inc., is headquartered in Columbia, Maryland. In 2011, Pfizer acquired King Pharmaceuticals. As part of that acquisition, Pfizer also acquired Meridian, which "develops and manufactures the EpiPen" sold by Mylan.[5]

29. Various other entities and individuals currently unknown to Plaintiffs may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy's objectives and unlawful conduct alleged herein.

30. The wrongful acts alleged to have been done by any one Defendant or coconspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

---

[5] Pfizer Inc., 2011 Financial Report, at 9, https://investors.pfizer.com/events-and-presentations/event-details/2012/2011-Pfizer-Annual-Report-to-Shareholders/default.aspx.

IV. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for the Approval of Drugs and Substitution of Generics for Brand Name Drugs

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA").[6] An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[7]

32. When the FDA approves a brand manufacturer's NDA, the brand manufacturer must list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance.[8]

33. Not all patents claiming the brand product can be listed in the Orange Book. FDA regulations indicate that patents whose information "must" be submitted "consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents." 21 C.F.R. § 314.53(b)(1). "Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates . . . must not be submitted to FDA." *Id.* Additionally, information on patents that only claim unapproved uses of a drug should not be submitted. 21 C.F.R. § 314.53(b)(1), (c)(2). The FDA does not confirm the patent listing

---

6 21 U.S.C. §§ 301-392.

7 21 U.S.C. §§ 355(a) & (b).

8 21 U.S.C. §§ 355(b)(1) & (c)(2).

information. Instead, the FDA performs merely a ministerial function in listing the patents in the Orange Book and relies on the truthfulness of the brand company in asserting in its NDA submission that a particular patent is eligible for Orange Book listing.

34. A patent applicant is subject to special oaths and duties, such as the duties of disclosure, candor, and good faith, during patent prosecution. A patents applicant is required to disclose to the Patent and Trademark Office ("PTO") "all information known . . . to be material to patentability" including with respect to prior art.[9] This duty extends to all inventors named on a patent application and any "attorney or agent who prepares or prosecutes the application," as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application."[10] Where fraud on the PTO "was practiced or attempted" or the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct" no patent should be granted.[11]

35. The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments Advanced the Goal of Providing Access to Generic Drugs

36. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand

---

9 *See* 37 C.F.R. § 1.56.

10 *Id*. § 1.56(c).

11 *Id*. § 1.56(a).

name drug may now file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA. For a generic drug to be designated "bioequivalent" to the brand name drug, the ANDA must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and achieves the same blood level in the same time period as the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating indicating that the AB-generic product is interchangeable with the brand named product at the pharmacy level.

37. Demonstrating bioequivalence to EpiPen is not required for FDA approval of a new entrant that is not interchangeable with EpiPen, but such a demonstration is important for a new entrant to convince EpiPen customers to switch to a new EAI.

38. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products are therapeutically equivalent and may be substituted for one another because they contain identical amounts of the same active ingredients in the same route of administration and dosage form, and they meet applicable standards of strength, quality, purity and identity. Thus, bioequivalence demonstrates that the active ingredients of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

39. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs and thereby reduce healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

40. The Hatch-Waxman Amendments achieved both goals. They substantially advanced the rate of generic product launches and ushered in an era of historic high profit margins

for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of prescriptions. By 2013, total prescription drug revenues were more than $329.2 billion and generic drugs accounted for 86% of prescriptions.

C. ANDA Patent Certifications Provide Incentives to Generic Manufacturers to Challenge Patents

41. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

42. When filing an ANDA, generic manufacturers must notify the relevant brand manufacturer of any Paragraph IV certifications they make.

43. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA by simply suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement

action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market.

44. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition from other generic versions of the drug.

45. Brand name manufacturers are incentivized to list patents in the Orange Book due to the high profit margins on brand name drugs and the erosion of those profits upon generic entry. Brand name manufacturers are motivated to sue any generic competitor that files an ANDA with Paragraph IV certifications even if the generic competitor's product does not actually infringe the listed patent and/or the patent is invalid and unenforceable. As a result, final FDA approval of an ANDA can be delayed for up to 30 months.

46. To encourage generic manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug.[12] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that unexpired patents listed in the Orange Book as covering the brand product are either invalid, unenforceable, or not infringed by the generic's

[12] 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

product, the FDA cannot approve a later-filing generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been forfeited.

47. Brand name manufacturers are incentivized to list patents in the Orange Book due to the high profit margins on brand name drugs and the erosion of those profits due to generic entry. Brand name manufacturers are motivated to sue any generic competitor that files an ANDA with Paragraph IV certifications even if the generic competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. As a result, final FDA approval of an ANDA can be delayed for up to 30 months.

D. Generic Competition Serves the Public Interest

48. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents compete with each other, prices decline even further.

49. Once a generic equivalent product hits the market, the generic quickly causes sales of the branded drug to diminish. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing. In a sample of drugs losing patent protection between 1991 and 1993, generics on average held a 44% market share after one year. By 2010, Intercontinental Medical Statistics ("IMS") industry data reflected that, on average, generics captured 80% of the brand's sales within six months.

50. Because of the strong potential for generics to diminish sales of brand name drugs, brand name manufacturers are motivated to extend their market dominance for as long as possible.

51. Because generics do not differ therapeutically from brands, the only meaningful basis for competition between them (or between generic versions of the same drug) is price. Experience and economic research demonstrate that the first generic manufacturer to launch prices

its product below the price of its brand counterpart.[13] When there is only one generic competitor on the market, their prices are typically between 10% and 20% lower than their brand counterparts. The discount increases dramatically as more generics enter: when there are multiple generics on the market, the discount off the brand price can be 80% or more. According to the FDA and the FTC, the greatest single drop in generic price occurs when the second generic enters the market.

52. Since the passage of the Hatch-Waxman Amendments, every state has adopted "generic substitution" laws that either require or permit pharmacies to substitute an AB-rated generic when presented with a prescription for its branded counterpart. As a result of these laws and other features of the pharmaceutical marketplace, when generic competition begins (so long as it is un-restrained), brand sales are rapidly converted to generic sales, with generics garnering 80% of unit sales or more within the first six months. The Federal Trade Commission (FTC) has found that, on average, generics capture 90% of brand unit sales within the first year of generic entry and, with multiple generics on the market, prices drop by 85%.

53. Absent generic competition, brand manufacturers typically sell their drugs at prices far above the marginal cost of production, generating profit margins of 70% and more, sometimes up to 98%. They can do this because, before generic competition, the brand has a monopoly on the drug. When the first generic enters, the brand's monopoly disappears, the generic charges less, and profit margins for the drug begin to shrink. When two or more enter, prices—and profit margins—drop much more precipitously.

---

[13] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at ii-iii, (Aug. 2011) ("FTC 2011 AG Study"), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; FTC Pay-for-Delay Study, at 1.

54. Brand manufacturers thus have an interest in forestalling generic competition for as long as possible, keeping monopoly profits for themselves. And first filers have an interest in being the only generic on the market for as long as possible, keeping generic sales for themselves.

55. When multiple generic competitors enter the market, the competitive process accelerates, and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[14]

56. A noted study of United States generic drug prices published in January 2019 found that:

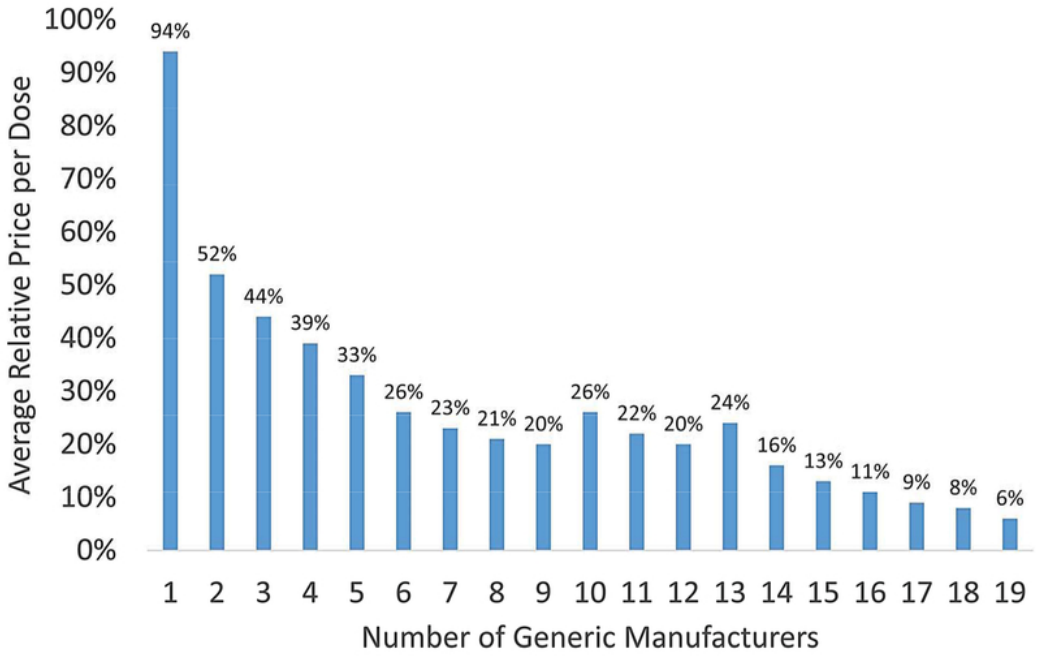
> [p]rices typically decrease rapidly with the entry of subsequent generic manufacturers. Generic drugs that entered the market between 2002 and 2014 reduced drug prices by 51% in the first year, and after a plateau in drug prices during the 180-day exclusivity when only the first generic drug manufacturer can market its drug, nearly all reductions in the price of oral medications occurred in the first eight months after generic entry. As the number of generic manufacturers within specific drug markets increases, drug prices continue to decline. A 2005 FDA analysis found that after patent and exclusivity expiration, the introduction of one generic manufacturer into the market reduced the price of the drug by only 6%. *With two generic manufacturers, the price reached 52% of the brand-name drug's price*.[15]

57. The study's authors represented these findings in a table entitled "Generic Competition and Drug Prices," showing the precipitous price drop after the second generic competitor enters the market:

---

[14] *FTC v. Actavis*, 570 U.S. 136, 144 (2013) (citation omitted).

[15] Ravi Gupta, et al., *Generic Drugs in the United States: Policies to Address Pricing and Competition*, 105 *CLIN. PHARMACOL. THER.* 2, 329-337 (Feb. 2019) (emphasis added), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355356/; *see also* Ryan Conrad and Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA Center for Drug Evaluation and Research (Dec 2019), https://www.fda.gov/media/133509/download.



58. In general, the more fully genericized the market for a particular drug, the lower the price will be. The presence of multiple generics in the market, competing with the brand and with each other, puts downward pressure on prices, to the benefit of purchasers and consumers.

E. Drug Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

59. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supra-competitive prices. Brand manufacturers are well aware of generics' rapid erosion of their brand sales, and thus seek to stall the impact of generic competition for as long as possible, sometimes resorting to illegal means.

60. One way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes known as "exclusion payment agreements" or "pay-for-delay agreements," which have

long concerned the FTC. Brand and generic manufacturers execute exclusion payment agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

61. In a typical exclusion payment agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

62. One method of payment to a first-filer generic company comes in the form of the brand company's promise to not launch an "authorized generic" version of the brand drug during the first-filer's 180-day exclusivity. An authorized generic is the brand drug, sold under the brand NDA, but sold by the brand or a licensee under generic trade dress. Because the brand manufacturer already has approval to sell its brand drug, it does not need to file an ANDA, or obtain any additional approval, to market an authorized generic. Multiple courts have recognized that ANDA filers have no right to be free from competition from an authorized generic.

63. In a 2011 report issued at the request of Congress, the FTC concluded that no-authorized-generic promises were being used as a payment by brands to generics for delayed generic entry, noting that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry."[16]

64. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand drug but is sold as a generic product—typically through either

[16] FTC 2011 AG Stud, at vi.

the brand manufacturer's subsidiary or through a third-party distributor. An AG is the brand drug but in a different package. One study noted, "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[17] Brand manufacturers sometimes begin selling AGs before the first-filer generic launches in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

65. Competition from an AG substantially reduces drug prices and the revenue of the first-filer generic (especially during the 180-day exclusivity period when no other generic can be on the market).

66. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[18]

67. For the brand company, an authorized generic launched during the first-filer's 180-day exclusivity (or longer) provides a low cost, low risk means to regain some of the revenue lost from the patent-cliff. For the first-filer however, an authorized generic launch has a huge negative impact on its revenue. A first-filer generally earns about 80% of its total income from a given generic product during its exclusivity period. An authorized generic, when launched during that time, will capture 50% or more of total generic sales during that period,[19] and will cause generic

---

[17] K. A. Hassett & R. J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, SONECON, p. 3 (May 2007).

[18] E. R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, v. 26, p. 796 & n.3 (May/June 2007).

[19] *Id.* at iii, vi, 41-48, 57-59.

prices to decrease as a result of the price competition.[20] A brand's promise not to launch an authorized generic during the first-filer's 180-day exclusivity is thus a very valuable payment to the first-filer, doubling its sales and more than doubling its revenues and profits (by removing a source of price competition). Correspondingly, a brand's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits for the brand that it would have otherwise earned by launching an authorized generic. Those revenues and profits are instead ceded, by way of the no-authorized-generic promise, to the first-filer.

68. For a first-filer generic, the difference between (1) selling the only generic product and (2) selling a generic product while competing against an authorized generic, for the first six months of generic marketing, constitutes a payment that can reach hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic and, by necessary implication, its absence.

69. A no-authorized-generic agreement between brand and generic drug companies—horizontal competitors—unjustly enriches both companies and injures consumers twice over: first, it prolongs the period during which only the high-priced brand is available; and second ensures that, once delayed generic competition begins, generic prices are artificially inflated by the absence of the authorized generic.

70. While a brand manufacturer's agreement not to launch an AG has tremendous financial value to a first-filer generic manufacturer, such an agreement, when used to induce the

[20] *Id.* at 5 n.21 (citing IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for PhRMA), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf).

first-filer to delay its own launch, injures drug purchasers in two ways: (1) purchasers are forced to pay the high brand prices for longer than they otherwise would have; and (2) purchasers pay more for the generic in the absence of the AG. In fact, the 2011 FTC AG Study shows prices with AG entry are lower during the 180-day exclusivity period.[21] Drug purchasers (including the proposed Class of direct purchasers) benefit from the lower prices caused by AG entry and are injured by the higher prices resulting from a lack of AG competition.

71. Freedom from an AG is exceedingly valuable to the first-filer because it hands over all generic sales at higher, supra-competitive prices. Consequently, some brand companies wield the right to launch an AG as a powerful tool to induce the first-filer generic to delay its entry. The promise of payment to the first-filer generic in the form of an agreement not to launch an AG is economically equivalent to the promise of a cash payment by the brand manufacturer to the generic manufacturer because refraining from launching an AG under the agreement effectively and predictably doubles the revenues and profits of that generic company from its generic drug, and the brand manufacturer forgoes the sales and revenues it otherwise would have made with its AG.

72. For a first filer seeking to sell a generic version of a brand product that sold hundreds of millions of dollars annually (like EpiPen), the difference between selling its generic alone, without having to compete against an AG, versus selling in competition with an AG, can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. "No AG" agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

---

[21] FTC 2011 AG Study, at 113-114.

F. Genuine Citizen Petitions to the FDA Serve a Public Good; Fraudulent Petitions Delay Generic Competition

73. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

74. Citizen petitions provide a forum for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product before, or after, its market entry.

75. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

76. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay the FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

77. The FDA's longtime practice had been to withhold ANDA approval until after completing its consideration of, and response to, a citizen petition regarding that ANDA. The former director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research ("CDER") acknowledged that it was "very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

78. Citizen petitions by rival companies rarely raise legitimate concerns about the safety or efficacy of generic products. They often request that the FDA impose additional, unnecessary, and costly requirements on a generic competitor to delay competitive generic entry and thereby preserve branded drug manufacturers' product monopolies after the end of statutorily prescribed patent or FDA exclusivity periods. Brand name companies frequently file these citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, earlier. This results in delay of approval of a pending ANDA for several months or longer while the FDA evaluates the merits of the citizen petition. Meanwhile, valid competition is foreclosed and purchasers bear the costs.

79. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies have sought to compensate for dwindling new product pipelines. In such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing, delaying the approval of the generic product while the FDA evaluates the citizen petition.

80. Delaying generic competition is a lucrative strategy for an incumbent manufacturer. Given the marketplace's preference for generic products over brand products, the cost of filing an improper citizen petition may be trivial compared to the value of securing even a few months delay in a generic rival's entry into the market.

81. Even the FDA, which is often hesitant to comment on existing law, has at times spoken out against the current citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of citizen petitions

that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."[22]

82. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. § 355(q) (the "FDAAA"), which added new section 505(q) to the FDCA providing that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The FDAAA does not, however, provide the FDA with additional resources that might allow it to more promptly respond to citizen petitions. A brand-name drug manufacturer can still use the citizen petition process to delay generic approval while the FDA considers whether the company's citizen petition implicates issues of public health, regardless of whether the petition has any real merit.

83. The FDA continues to have serious concerns about the abuse of the citizen petition process for anticompetitive purposes and noted in a 2020 report to Congress that "the Agency continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[23]

---

[22] Remarks of FDA Chief Counsel Sheldon Bradshaw before the Generic Pharmaceutical Association's (GPhA) policy conference in September 2005, https://www.pharmacytimes.com/publications/gpr/2005/GPR_2005-12/GPR_2005-12_3282.

[23] U.S. Food & Drug Administration, Twelfth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2019 (2020), www.fda.gov/media/143518/download.

G. EAIs and FDA Approval

84. Because EAIs must be prescribed by a medical professional, there is a lengthy 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.

85. Typically, prescriptions for EAIs 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 would require additional training if they were to use a new product.

86. Mylan itself noted the high regulatory hurdles for a generic to be listed as an AB-rated substitutable EAI drug device. Even if a generic device is approved by the FDA and shown to be bioequivalent to the EpiPen, without an AB-rating to EpiPen, a pharmacist would not be able to automatically substitute the generic EAI when a patient's prescription specifies EpiPen.[24] A doctor would need to write a new prescription that specifies the alternative EAI.

V. STATEMENT OF FACTS

A. Epinephrine Auto-Injectors

87. Anaphylaxis is a potentially life-threatening allergic reaction where a person's immune system releases a flood of chemicals causing the person to go into shock with a sudden drop in blood pressure and breathing problems.

88. Symptoms of anaphylaxis may include a rapid and weak pulse, nausea, vomiting, and a rash. Anaphylaxis may occur within seconds or minutes of a person's exposure to an allergen,

[24] *See* U.S. Food & Drug Admin., Orange Book Preface, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

such as peanuts or bee stings, or from exercise or unknown substances. Each year, allergic reactions account for about 200,000 emergency room visits.[25]

89. It has been estimated that 1,500 people die from anaphylaxis every year.[26] According to Mylan, 43 million people in the United States are at risk for life-threatening allergic reactions due to allergic sensitivities.[27] Mylan also has stated that "1 in 13 children [are] affected by food allergies."[28]

90. Epinephrine is very effective at treating anaphylaxis, but it must be administered immediately. A delay in receiving epinephrine of as little as 30 minutes can result in death.

91. In the vast majority of cases, an EAI is the most effective device for quickly administering epinephrine. In the United States, EAIs are available only by prescription.

92. An EAI injects epinephrine into a muscle through a device's needle. The diagram below shows how one EAI is constructed and allows for injection of epinephrine into a muscle through a device's spring-loaded needle:

---

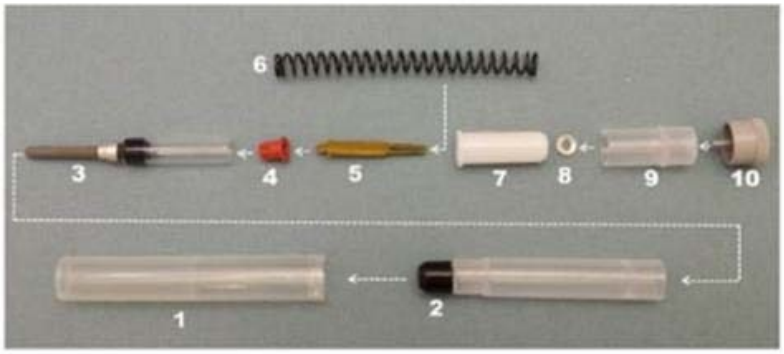
[25] Selena Larson, *Outrageous EpiPen prices lead some people to make their own*, CNNMoney, Sept. 24, 2016.

[26] Press Release, Mylan, 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), https://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).

[27] *See* Reviewing The Rising Price of EpiPens: Hearing Before the H. Comm. on Oversight & Gov't Reform at 17 (Sept. 21, 2016) (Statement of Heather Bresch, CEO of Mylan), https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/pdf/CHRG-114hhrg24914.pdf.

[28] 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).

Rev 1 EpiPen® Complete Device



Rev 1 EpiPen® Part Breakdown

1. Housing
2. Sleeve
3. Cartridge and Stopper
4. Stopper Driver
5. Plunger (formed of two laser cut brass sheet parts)
6. Drive Spring
7. Release Collar
8. Thrust washer
9. Rear Collar
10. Safety Cap

93. In the 1970s, Survival Technology, Inc., developed the first auto-injector drug device, called the ComboPen, to administer a nerve agent antidote for the United States military. It subsequently modified the device to deliver epinephrine, thus creating the EpiPen antidote. The ComboPen was later modified to deliver epinephrine, thus creating the EpiPen.[29]

94. The FDA approved the EpiPen on December 22, 1987, under New Drug Application 019430.

95. In 1996, Survival Technology, Inc. merged with Meridian. One year, later, Meridian sold the exclusive right to market and distribute the EpiPen in the United States to Dey

[29] Matt Reimann, *The Story of the EpiPen: From Military Technology to Drug-Industry Cash Cow,* TIMELINE (Aug. 20, 2016), https://timeline.com/epipen-technology-drug-industryb28d19036dee#.seg6n7dls.

Pharma LP.[30] At the time, Dey Pharma LP was a subsidiary of Merck KGaA, a German multinational pharmaceutical company.

96. In 2007, Mylan acquired Dey Pharma LP (later renamed Mylan Specialty). Since that time, Mylan has marketed, distributed, and sold the EpiPen in the United States. According to Mylan, the EpiPen "is used in the treatment of severe allergic reactions" and "is an epinephrine auto-injector that has been sold in the United States. and internationally since the mid-1980s."[31]

97. "[F]or doctors, who write prescriptions for the name they know best, the EpiPen brand 'is like Kleenex,' says Robert Wood, a pediatric allergist at Johns Hopkins University School of Medicine."[32]

98. The Supply Agreement between Mylan and Meridian obligates Meridian to supply Mylan with the requested quantity of EpiPen and for Meridian to be compensated on a per-unit basis. Under the Agreement, Meridian was required to prosecute and maintain any patents or patent applications.

99. The EpiPen provides a 0.3 mg dose of epinephrine, while the EpiPen Jr. contains a 0.15 mg dose. The EpiPen Jr., for kids, has a retail price that is the same as the EpiPen, despite containing half the medicine (0.15 mg instead of 0.3mg) of the EpiPen. EpiPens have a one-year expiration period and patients are advised to replace them after their expiration date.

---

[30] Meridian Medical Technologies, Annual Report (Form 10-K) (July 31, 1997); Marilyn Case, *EpiPen Recall Points to Broader Concerns*, WALL ST. J. (May 18, 1998), http://www.wsj.com/articles/SB895440623631960000.

[31] Mylan N.V. 10-K (2015), https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231xdo c.htm.

[32] Cynthia Koons and Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Busines*s, BLOOMBERG (Sept. 23, 2015), https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business.

100. Mylan has continuously dominated the EAI market since purchasing the rights to market the EpiPen. In December 2012, Mylan touted 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."[33]

101. Mylan launched an authorized generic of the EpiPen in November 2016. EpiPen had been the number-one prescribed EAI in the United States for over 25 years prior to Mylan's launch of its authorized generic in December 2016.

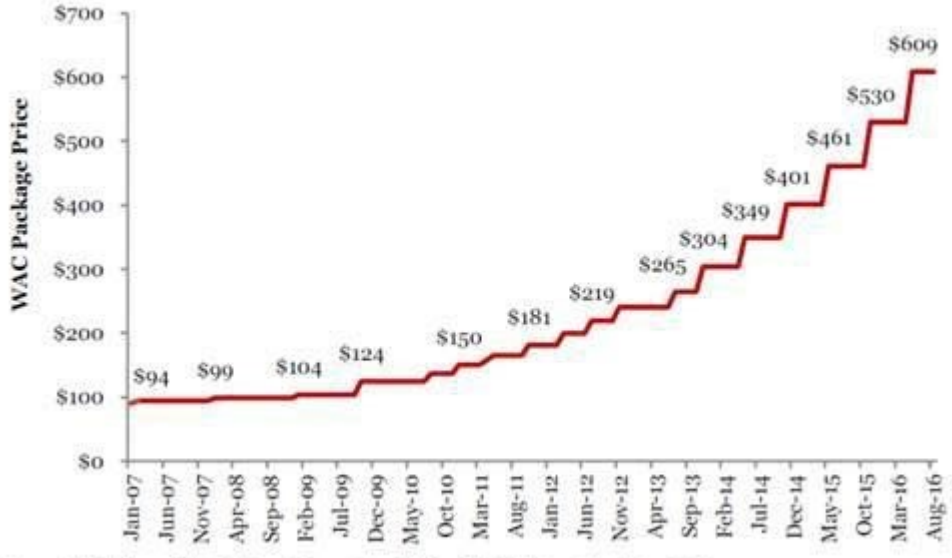
102. At the time of launch, Mylan's authorized generic cost $300 per two-pack—less than half the price of the EpiPen 2-pack. Mylan launched its authorized generic EpiPen to slow the expected decline in the revenues received from its EpiPen franchise that would occur after Teva launched its AB-rated generic EpiPen.

103. Together, the EpiPen and Mylan's authorized generic account for approximately 72% of the $2.5 billion dollar market for EAIs in the United States.

104. Beyond Mylan's EpiPen market share, Mylan's monopoly power is evidenced by its ability to raise prices without any loss of sales. Between Mylan's purchase of the right to sell and distribute the EpiPen in 2007 and August 2016, it raised EpiPen prices more than six-fold:

[33] Press Release, Mylan Inc., Incidence of Anaphylaxis During Winter Events Highlights Importance of Adding a Preparedness checklist to Holiday Planning, at 1 (Dec. 18, 2012), https://investor.mylan.com/static-files/36b8bfcc-38d1-4a5d-b925-141f3ef63236.

Exhibit 1. EpiPen WAC Package Price



Source: Medi-Span, Clinical Drug Information, LLC and Wells Fargo Securities, LLC

105. In 2021, the EpiPen costs consumers over $650 per package.

106. Between 2013 and 2016, sales of EpiPens in the United States surpassed $1 billion annually.[34]

107. The drastic increases to EpiPen's price are not driven by the cost of producing the EpiPen. In fact, the EpiPen can be produced inexpensively. According to Kevin Deane, head of medical technologies for PA Consulting Group, a global technology and design firm that sold a drug delivery technology company to Pfizer in 2004, "the base components for each EpiPen, including the plastic cap, tube, and needle, might cost between $2 to $4 to purchase." Moreover, the EpiPen contains "essentially [the] same core technology that [has been] there for many

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

years."[35] In addition, two engineering industry experts peg the total cost of making an EpiPen 2-Pak at between $8.02 and $10.03, and that "even include[s] the bright-yellow box."[36]

B. Defendants Unlawfully Delayed Generic Competition

108. Prior to December 2020, Meridian held the patents on the EpiPen, which were transferred to Mylan at that time. Defendants' control over these patents means that competitors who seek to launch a generic EAI product prior to 2025 must certify, through the filing of a Paragraph IV certification with the FDA, that each patent is invalid or will not be infringed by that competitor's EAI drug device.

109. The patent holders have filed three patent infringement lawsuits against potential competitors in the EAI drug device market, claiming that potential competing products infringe patents protecting the EpiPen through 2025. Defendants used these patent litigations and resulting settlements as a means to delay the entry of competitor products in the EAI market.

110. During a question-and-answer period of its first quarter 2009 Earnings Call with Wall Street analysts, Mylan CEO Heather Bresch ("Bresch") was asked about competition to the EpiPen and whether that posed a challenge to Mylan's earnings. In response, Bresch announced that Mylan was adding another patent to the already-patented EpiPen device that "will also put in another barrier to entry because that now that market preferential would be the needle protected device and drug of which we have IP and stuff around. So I just think it is a very, very difficult

---

[35] Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than $30*, NBC NEWS (Sept. 6, 2016), http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costsno-more-30-n642091.

[36] Tracy Seipel, *EpiPen Outrage: Silicon Valley Engineers Figure Real Cost to Make Lifesaving Auto-Injector Two-Pack—about $8*, MERCURY NEWS (Oct. 1, 2016), https://www.mercurynews.com/2016/10/01/epipen-outrage-silicon-valley-engineers-figure-true-cost-to-make-lifesaving-auto-injector-about-10/.

hurdle to get through, and so feel confident that EpiPen is in good shape."[37] Bresch further assured the Wall Street analysts that Mylan was confident that no generics could compete because any generic has "to match identically" the underlying drug or device, which is "really the hurdle when you talk about a drug and device product such as EpiPen."[38] Shortly after this call, Meridian—not Mylan—secured the '432 patent.

111. In 2011, Pfizer acquired King Pharmaceuticals, Inc. As a part of that acquisition, Pfizer acquired a subsidiary, Meridian, which develops and manufactures the EpiPen sold by Mylan.

112. Prior to December 2020, Pfizer owned the patents protecting the EpiPen and was the contract supplier of the product. Mylan owns the trademarked brand names and controls the worldwide marketing and sale of the products. The divided intellectual property ownership of the EpiPen and licensing agreements resulted in the two companies working collaboratively to enhance sales volume and profitability. If the EpiPen patents were invalidated, or if other competitors gained market share, both companies stood to lose.

113. Since Mylan acquired the rights to market and sell the EpiPen from Merck in 2007, it has purchased its EpiPens exclusively from King (that supplies the generic epinephrine), and King's subsidiary Meridian. King supplied the generic epinephrine, and Meridian supplied the injection pens.

114. After Pfizer acquired King (and thereby Meridian) in October 2010, Pfizer agreed to continue supplying the device to Mylan under non-public terms. On information and belief, that

---

[37] Mylan Inc., Q1 2009 Earnings Call Transcript, SEEKING ALPHA (May 1, 2009), http://seekingalpha.com/article/134619-mylan-inc-q1-2009-earnings-call-transcript?part=single.

[38] *Id*.

agreement provides for the sale of EpiPens to Mylan at a contract price which has escalated along with EpiPen's market dominance, rising from roughly $80 per unit to $86 per unit. Pfizer's revenue on sales of the EpiPen also increased with EpiPen's market dominance[39]:

Year	Unit Sales Volume of EpiPen	Pfizer's EpiPen Revenue	Unit Price
2012	3,310	$263M	$79.50
2013	3,416	$273M	$80.00
2014	3,656	$294M	$80.00
2015	3,930	$339M	$86.00

115. In or around July 2013, Mylan Specialty LP replaced Meridian as the sponsor of the EpiPen patents in the Orange Book. Although the reasons for the change were unclear, it demonstrates further concerted action by Mylan and Pfizer to share in the benefits and burdens of the EAI market monopoly.

1. Teva Litigation

116. Teva filed ANDA No. 90-0589 seeking approval to market a generic EpiPen in December 2008.

117. At the time Teva submitted its ANDA, Meridian held a patent on the auto-injector component of the brand EpiPen product. On August 28, 2009, Mylan and King/Meridian conspired to have King and Meridian sue Teva in *King Pharm., Inc. v. Teva Parenteral Med., Inc.,* No. 1:09-cv-00652 (D. Del.), alleging infringement of U.S. Patent No. 7,449,012 (the "'012 Patent"). Mylan

[39] *See* Pfizer's Financial Statements, Appendix A, 2012-2015.

and Pfizer entered into a Common Interest Agreement in connection with the patent infringement litigation against Teva.[40]

118. On November 11, 2010, King and Meridian amended their complaint to include a claim of infringement on U.S. Patent No. 7,794,432 (the "'432 Patent").

119. King and Meridian subsequently dropped all claims related to the alleged infringement of the '012 patent, leaving only the claims related to the '432 patent.[41]

120. Pfizer reported the following to investors in 2011:

> King brought patent-infringement actions against Sandoz in the U.S District Court for the District of New Jersey in July 2010 and against Teva Pharmaceutical Industries and Intellijject, Inc. (Intellijject) in the U.S. District Court for the District of Delaware in August 2009 and January 2011, respectively, as the result of their abbreviated new drug applications with the FDA seeking approval to market epinephrine injectable products. The two actions in Delaware subsequently were consolidated. Sandoz and Teva Pharmaceutical Industries are challenging and Intellijject challenged two patents, which expire in 2025, covering the next generation auto-injector for use with epinephrine that is sold under the EpiPen brand name. In February 2012, the action against Intellijject was settled. Under the settlement agreement, Intellijject may launch its epinephrine injectable product no earlier than November 15, 2012, subject to final approval by the FDA.

121. Following discovery, the case against Teva proceeded to a four-day bench trial in March 2012.

122. According to Pfizer's counsel, the most important claim terms at issue in the bench trial, all present in claims 19 or 20 of the '432 Patent, were "a first locked retracted position," the

---

[40] *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices & Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, ECF No. 2381 at 31 (Memorandum and Order) (D. Kan. Jun. 23, 2021) (the "Consumer Class Summ. J. Mem.").

[41] *See King Pharm., Inc., et al, v. Teva Parenteral Med., Inc., et al.*, No. 1:09-cv-00652, ECF No. 134 (Plaintiffs' Unopposed Motion to Dismiss Count I) (D. Del. Nov. 3, 2011).

claim that "energy released from the stored energy source to drive the needle during the medicament dispensing operation is not transferred to the needle cover," and "attenuating kickback."

123. Teva argued that its generic version of the next-generation EAI, as submitted in its ANDA, did not infringe the '432 Patent for a number of reasons. First, Teva's generic relied on manual insertion of the needle into the patient, not requiring "a stored energy source capable of driving the plunger within the cartridge to dispense the medicament through the needle assembly." Second, Teva's generic equivalent did not have a needle cover that locks in place, as opposed to the '432 Patent which requires "the needle cover having a first locked retracted position." Third, Teva's generic equivalent did not have energy released from the stored energy source, in direct contradiction to the claims of the '432 Patent.

124. In addition to the obvious differences in Teva's auto-injector, as well as favorable claim constructions by the court, the bench trial included evidence of three pieces of "prior art references," which Teva contended invalidated the '432 Patent.

125. The parties executed a term sheet to settle the litigation on April 26, 2012. Under the terms of the settlement, Teva agreed to delay the launch of its generic EAI for three years, until June 22, 2015, subject to FDA approval.[42] While not a party to the litigation, Mylan executed a covenant not to sue attached to the term sheet and was heavily involved in negotiating the term sheet.

[42] Press Release, Mylan Inc., Mylan and Pfizer Announce Epinephrine Auto-Injector Settlement Agreement with Teva, (Apr. 26, 2012), http://newsroom.mylan.com/press-releases?item=123144.

126. Defendants knew that an agreed-to delay with Teva would be subject to the Hatch-Waxman Act's 180-day exclusivity award, which grants a six-month exclusivity period to the first generic to challenge a brand firm's patent by claiming it is invalid or not infringed. The exclusivity period does not begin to run until the first-filing generic enters the market. Defendants made use of this exclusivity award to foreclose all other EAI generic competition for the delay period. Under the agreement, Teva would not launch its product until June 22, 2015. Because of Teva's exclusivity award, no other generics seeking ANDA approval based on the EpiPen could enter the market during the delay period.

127. Upon information and belief, in settling the Teva litigation, Defendants and Teva entered into an unlawful agreement whereby Defendants provided significant consideration, incentives, and benefits to Teva in the form of a settlement of the patent litigation related to Nuvigil, as discussed below, to delay bringing their competing product to market.

128. It can be reasonably inferred that Defendants made a substantial "reverse payment" to Teva to convince it to delay bringing its competing generic auto-injector to market based on the facts, including: (a) the Teva Court's *Markman* rulings on the interpretation of the '432 patent were favorable to Teva; (b) at the time of a settlement, a full bench trial had been conducted and further anticipated litigation expenses would have been marginal compared to expenses already incurred at the time of the settlement; and (c) no rational economic actor with a viable product (and who had spent millions of dollars developing it) would refrain from entering a lucrative "blockbuster" market for 36 months unless it received substantial value in return; and (d) on the same day, Teva settled an infringement lawsuit against Mylan relating to Mylan's attempt to market a generic version of Teva's Nuvigil, another blockbuster drug involving nearly $1 billion

in annual sales. Other publicly available information from the Federal Trade Commission also supports the reasonable inference that the Teva settlement was an illegal pay-for-delay scheme.

129. The Teva settlement was submitted to the FTC for review in 2012.

130. A 2012 Federal Trade Commission report explains that the year 2012 saw "a record number of settlements involv[ing] pay-for-delay agreements."[43] This same report found that in patent settlements involving a "first-filer"—as Teva was here—a majority of the settlements involved explicit compensation in return for delayed entry.

131. On April 26, 2012, Mylan issued a press release in conjunction with Pfizer about the Teva settlement[44]:

> Mylan Inc. (Nasdaq: MYL) and Pfizer Inc. (NYSE: PFE) today announced that Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Teva that will resolve pending patent litigation related to its abbreviated new drug application (ANDA) for a generic epinephrine auto-injector.
>
> According to the terms of the settlement, Teva may launch a generic epinephrine auto-injector covered by its ANDA on June 22, 2015 or earlier under certain circumstances, subject to receipt of approval from the U.S. Food and Drug Administration. Teva currently does not have tentative approval from the FDA for its epinephrine auto-injector product.

132. Meridian manufactures the EpiPen Auto-Injector and Mylan Specialty markets and distributes the product in the United States. Mylan was not a signatory to the settlement agreement with Teva, but Mylan did sign a Form of Covenant Not to Sue and Mutual Releases, which was

---

[43] See FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreement Filed in FY2012, https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement.

[44] Press Release, Mylan Inc., Mylan and Pfizer Announce Epinephrine Auto-Injector Settlement Agreement with Teva, (Apr. 26, 2012), http://newsroom.mylan.com/press-releases?item=123144.

attached to the settlement. Also, under the Supply Agreement between Mylan and Pfizer, parties are required to notify each other of potential infringement and "jointly determine in good faith the appropriate course of action[.]"[45]

133. On July 26, 2012, Bresch stated in an earnings call with company analysts, "So we certainly have seen a benefit [to growing the EpiPen market] and obviously, now with the runway absolutely clear for us through 2015, through our settlement with Teva, I can assure you, we are going to continue as we see [the] response continue to invest in EpiPen as a franchise."

134. It is reasonable to infer that the settlement was an unlawful pay-for-delay agreement entered into for the benefit of all Defendants, and that while Mylan was not a party to the patent lawsuits, it was participating in the concerted action as addressed throughout this Third Amended Complaint. The trial court record shows that the '432 patent would likely have been found invalid, which would have removed the most significant barrier to market entry for Teva or any other putative generic manufacturer. The settlement allowed Defendants to continue building "the franchise" without competition and making the market more lucrative for Teva when and if it finally came to market.

135. At the same time as the EpiPen patent litigation, Teva was involved in patent litigation against Mylan related to Mylan's ANDA to market a generic version of the drug Nuvigil (armodafinil)—a prescription drug used to "improve wakefulness in patients with excessive sleepiness."[46]

---

[45] ECF No. 2381 at 40 (Consumer Class Summ. J. Mem.).

[46] *See* Complaint, *Cephalon, Inc. v. Mylan Pharms., Inc.*, No. 1:09-cv-00954, ECF No. 1 (D. Del. Dec. 11, 2009).

136. The valuable consideration Teva received in exchange for dropping its meritorious challenge to the EpiPen patents was the settlement of the patent litigation between Teva and Mylan relating to the blockbuster drug Nuvigil.

137. In December 2009, Cephalon, Inc. ("Cephalon") filed a patent infringement action against Mylan based on Mylan's ANDA for generic Nuvigil—*Cephalon, Inc. v. Mylan Pharms., Inc.*, No. 1:09-cv-00954 (D. Del.). Nuvigil was a critical drug for Cephalon, accounting for nearly $1 billion in sales annually, or roughly half the company's total sales.

138. Teva acquired Cephalon in October 2011, while the Nuvigil litigation was pending. Like the EpiPen litigation, the Nuvigil lawsuit was filed in the District of Delaware and proceeded at a pace similar to the EpiPen litigation. By the time Teva acquired Cephalon, the Nuvigil litigation was in full swing, and a trial was scheduled for June 2012.

139. Cephalon's filing of patent litigation challenging Mylan's Nuvigil ANDA triggered the Hatch-Waxman Act's 30-month stay, meaning the FDA could not finally approve Mylan's ANDA while the Nuvigil litigation was ongoing. 21 U.S.C. §§ 355(j)(5)(B)(iii), (c)(3)(C). During the 30-month stay period, the FDA tentatively approved Mylan's ANDA to manufacture and sell a generic version of Nuvigil, signifying that Mylan's ANDA met substantive requirements for final approval.

140. Leading up to May 2012, Mylan maintained its ability to launch its generic product upon approval.[47]

141. On April 26, 2012—the same day the term sheet resolving the Teva EpiPen ANDA litigation was agreed to—Teva and Mylan entered into a term sheet to settle the Mylan Nuvigil

[47] ECF No. 2381 at 51 (Consumer Class Summ. J. Mem.).

ANDA litigation and to delay market entry of Mylan's generic version of Nuvigil until June 1, 2016. Similar to EpiPen, Nuvigil was also a blockbuster drug and generic delay of several years was worth hundreds of millions (if not billions) of dollars to Teva.

142. The Nuvigil settlement came as a surprise to financial analysts monitoring the litigation. During a May 9, 2012 Teva earnings call, one analyst observed: "I was a little surprised to see you settle for generic entry on Nuvigil in 2016, especially with what you just said about the first positive bipolar study." Teva's decision to agree to 2016 generic entry appears more rational when viewed in conjunction with the EpiPen settlement.

143. The EpiPen and Nuvigil ANDA settlements were negotiated by the same individuals and entered into on the same date. Neither settlement makes economic sense by itself. Upon information and belief, Defendants gave Teva years of additional Nuvigil exclusivity in exchange for Teva's agreement not to market its AB-rated generic EpiPen until June 22, 2015.

2. Intellijject/Auvi-Q Litigation

144. On November 30, 2009, Sanofi-Aventis U.S. LLC ("Sanofi") announced it had obtained the rights to Intellijject's EAI (originally called the "e-cue" but later renamed Auvi-Q).

145. Under the license, Sanofi would be responsible for manufacturing the commercializing the product while Intellijject would be responsible for ongoing development and obtaining regulatory approval.

146. Intellijject submitted an NDA for its EAI on September 29, 2010. The EpiPen and Auvi-Q were very different devices, both in appearance and operation.

147. King filed a patent infringement lawsuit against Intellijject on January 19, 2011, to block FDA approval of its NDA.[48] King alleged the Auvi-Q device infringed the '432 Patent,

[48] *See King Pharm., Inc. v. Intellijject, Inc.*, No. 09-cv-652-GMS (D. Del.).

entitled "Automatic Injector with Kickback Attenuation," which related to a mechanism to cover the needle after use.[49]

148. The '432 Patent was not obtained by Meridian until September 14, 2010, over a year after Intellijject began developing its EAI and only two weeks before Intellijject filed its NDA.

149. Meridian listed the '432 Patent in the Orange Book on September 15, 2010, the same day it was issued by the PTO. On the other hand, Meridian had not listed the '012 Patent in the Orange Book for more than eight months after the patent was granted. Upon information and belief, Meridian rushed to submit the '432 Patent in the Orange Book so it would be listed before Intellijject filed its NDA.

150. On August 1, 2011, Intellijject announced that the FDA had given the Auvi-Q tentative approval. According to Intellijject's press release[50]:

> Obtaining a tentative approval means that the product review is complete and the submission met the FDA's requirements to be approved. The FDA reserves final approval of the product, however, until all exclusivity or patent challenges have been resolved, specifically the current patent litigation brought against Intellijject by King Pharmaceuticals, Inc. (King) and Meridian Medical Technologies, Inc. (Meridian). Final FDA approval is required before a product can be marketed in the United States.

151. Upon information and belief, Defendants conspired with each other, and with Intellijject and Sanofi, to enter into an anticompetitive agreement whereby Defendants provided significant consideration, incentives, and benefits to Intellijject and Sanofi to delay bringing their competing product to market.

---

[49] Auvi-Q's needle retracts and uses an entirely different mechanism to prevent accidental sticking with its needle.

[50] Press Release, Intellijject, Inc., FDA Tentatively Approves Intelllijject's Lead Produce, e-cue™ (Aug. 1, 2011), https://www.prnewswire.com/news-releases/fda-tentatively-approves-intellijects-lead-product-e-cue-126518718.html.

152. On February 16, 2012, about two months before the Teva settlement, Mylan and Pfizer (again jointly) announced they had reached a settlement with Intellijject over their patent litigation. Despite not being a party to the litigation or the settlement agreement, Mylan drafted the press release announcing the settlement.[51] Although the terms of the deal are confidential, the parties did reveal that the agreement prevented Intellijject and Sanofi from launching their Auvi-Q device for another nine months, until November 15, 2012. Upon information and belief, Intellijject and Sanofi agreed to this in exchange for valuable consideration. The relatively short duration of delay before entry of the Auvi-Q likely indicates the strength of Intellijject's defenses to the patent litigation.

153. On August 10, 2012, the FDA granted final approval of Intellijject's NDA, but pursuant to the settlement, Sanofi could not sell its competing EAI product, Auvi-Q, until after November 15, 2012.

3. Sandoz Litigation

154. In 2010, Sandoz, Inc. ("Sandoz") attempted to enter the market through a generic alternative to EpiPen by filing an ANDA. King filed a patent infringement suit against Sandoz in response to the ANDA filing. The litigation stalled, with the court entering an order staying the FDA process and administratively terminating the action, to be reopened upon letter request by any of the parties.[52] No party has requested that the case be reopened.

4. Mylan's Meritless Citizen Petition

155. Further seeking to delay competition from a generic equivalent in the EAI market, in January 2015, six months before Teva would have been permitted under the settlement

---

[51] ECF No. 2381 at 56 (Consumer Class Summ. J. Mem.).

[52] *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 10-cv-3568, ECF No. 66 (D.N.J. May 10, 2011).

agreement to launch its generic, Mylan 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.[53] The citizen petition noted that "the design and operating principles of the Teva proposed product differ significantly from the EpiPen" asserted that Teva should provide "at a minimum, very carefully designed human factors studies that would demonstrate the Teva product's safety and effectiveness and its comparability to the EpiPen[.]"[54] The FDA denied Mylan's citizen petition without comment on June 15, 2015.

156. A leading antitrust scholar of Rutgers Law School, Michael Carrier, noted that "Mylan received significant unwanted attention in 2016 for its price hike for EpiPen, but its citizen petition escaped notice. The lifecycle of EpiPen reveals how Mylan used citizen petitions along with settlements to delay generic entry."[55] He continued:

> [A]s Teva's entry loomed, Mylan reached into its toolkit to pull out a citizen petition, which it filed on January 16, 2015, a mere six months before Teva was scheduled (pursuant to the settlement) to enter the market. In its petition, Mylan contended that Teva should be required to demonstrate that its product was the "same as" Mylan's EpiPen. In other words, even though the parties had already agreed through settlement to delay Teva's generic entry for more than three years, Mylan sought to *further* delay the entry of Teva's generic through its citizen petition.
>
> In addition to its January 2015 petition, the company waited almost *five months* after filing and only weeks before the FDA was required to respond, until May 2015, to supplement its petition with a 48-page independent study purportedly showing that patients would not use Teva's generic product correctly.

---

[53] U.S. Food & Drug Admin., Citizen Petition Denial Response from FDA CDER to Mylan Specialty L.P. (June 15, 2015).

[54] Mylan Specialty, L.P., Citizen Petition at 3 (Jan. 16, 2015), https://www.washingtonpost.com/blogs/wonkblog/files/2016/09/Citizen_Petition_From_Mylan_Specialty_L_P_.pdf.

[55] Michael A. Carrier, et al., *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (Dec. 2016).

> Given that Teva's generic product had been in development for at least *six years* before the petition's filing, this late-filing of a supplemental study implicates significant timing questions. Why would such a study be submitted only weeks before the FDA was required to respond under the FDA's 150-day clock?[56]

157. Mylan waited until just before the FDA's response was due to submit a supplemental "study" from a consulting firm. Although the study purportedly found that Teva's device would not be effective, the study had numerous flaws that demonstrate Mylan was not acting in good faith in relying on it. For example, (a) the study lacked a control group; (b) the study did not use the actual generic device, but instead used a prototype; (c) the study used a small number of participants; and (d) the researchers merely told the participants to watch a video rather than actually use the prototype.[57] Professor Carrier further opined that,

> Shedding even more light on the questionable petition and supplemental study is its timing. In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008. And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010. This material included "detailed product descriptions, drawings, and instructions for use" for Teva's proposed generic.
>
> At the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.
> …
>
> We think it reasonable to conclude that Mylan's (1) filing of a petition years after invariably knowing about Teva's generic, (2) filing of a petition calculated to delay entry after settlement, and (3) late-filing of a supplemental study together comprised a strategy to

---

[56] *Id*.

[57] Ed Silverman, *How Mylan Tried to Keep Teva from Selling a Generic* EpiPen, STAT (Aug. 31, 2016), http://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/.

> delay Teva's ANDA approval ***beyond*** the ***already-delayed*** agreed entry date of July 22, 2015.[58]

158. Mylan's citizen petition relied on a medical statement from Dr. Eli Meltzer that sought to downplay the generic device from Teva. Meltzer, however, was paid roughly $95,000 in fees in 2014 and 2015 by Mylan, according to the Open Payments federal database.

159. In addition to the citizen petition, Meridian wrote letters to the FDA in 2012 and 2013 attempting to delay approval of Teva's pending ANDA.

160. Although the FDA ultimately rejected the citizen's petition, these submissions and Meridian's letters delayed the approval for Teva's generic EpiPen products.

5. The Availability of Teva's AB-Rated Generic EpiPen Was Substantially Delayed as a Direct Result of Defendants' Misconduct

161. On account of negotiations relating to the EpiPen ANDA settlement and the settlement itself, Teva dropped the ball between 2011 and 2014 by failing to aggressively pursue its ANDA application or timely respond to the FDA's inquiry regarding same. During this time period when settlement negotiations between Teva and Defendants were ongoing, Teva's responsiveness to the FDA's requests noticeably slowed. By way of example, in one instance Teva waited until August 2014 to respond to a February 2011 deficiency letter from the FDA.

162. Upon information and belief, had Teva responded to the FDA's requests regarding its ANDA application in a timely manner during this period, the FDA would have completed its review of Teva's ANDA application by 2014, if not earlier.

---

[58] Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. Online 53, 64-66 (2017) (emphasis in original).

163. But for the EpiPen settlement, Teva's AB-rated generic EpiPen would have entered the EAI market in March 2014 or, at the latest, January 2015. Teva's internal documents from 2011 and early 2012 indicate it anticipated to launch its AB-rated generic EpiPen by 2014.

C. Defendants Exploited Their Market Dominance by Charging Supra-Competitive Prices for EpiPens

164. The goal, purpose and effect of Mylan's conduct described herein was to artificially inflate prices for EpiPen and for Mylan's generic EpiPen.

165. In December 2012, Mylan boasted 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."[59] On August 1, 2013, Mylan told investors that the EpiPen had a "93.3% market share."[60]

166. Since late 2009, Mylan has raised the price of the EpiPen at least 15 times. On October 12, 2009, Mylan raised the price of two EpiPens to $124. In October 2011, two years and four price increases later, Mylan increased the price of an EpiPen 2-Pak to $181. After four more price increases, by July 17, 2013, an EpiPen 2-Pak cost $265. By November 2014, following three additional price increases, the EpiPen 2-Pak cost $401.

167. Mylan hiked prices by 15% in July 2013. It then tacked on four more successive 15% increases in February 2014, September 2014, April 2015, and November 2015 taking the price from $304 all the way up to $530 in the course of less than 30 months.

---

[59] Press Release, Mylan Specialty, 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.

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

168. After the EpiPen price had more than doubled by 2014, a group of Mylan executives repeatedly raised concerns internally over Mylan's profiteering at the expense of children. When confronted with those concerns, Mylan Chairman Robert Coury reportedly "raised both his middle fingers and explained, using colorful language, that anyone criticizing Mylan, including its employees, ought to go copulate with themselves."[61]

169. In 2014, Mylan executed a tax inversion to transform itself on paper into a Netherlands corporate shell. Upon information and belief, Mylan did this in order to avoid paying taxes in the United States. "[Tax] filings also show that under a special, one-time stock grant created in 2014, top executives—including Ms. Bresch—stand to reap further riches at least partly on the back of price increases on the EpiPen," and "the timing of the one-time stock grant to executives is striking—especially when set against the history of EpiPen price rises."[62]

170. "Mylan began significantly stepping up the pace of its EpiPen price increases just a few months after the company announced the special grant in February 2014. While price increases in the previous four years averaged 22% annually, in 2014 and 2015, Mylan increased EpiPen prices 32% each year."[63]

171. Mylan then continued to hike the price of the EpiPen 2-Pak throughout 2015 and into 2016. One of those increases came in November 2015—just one month after the Auvi-Q was

---

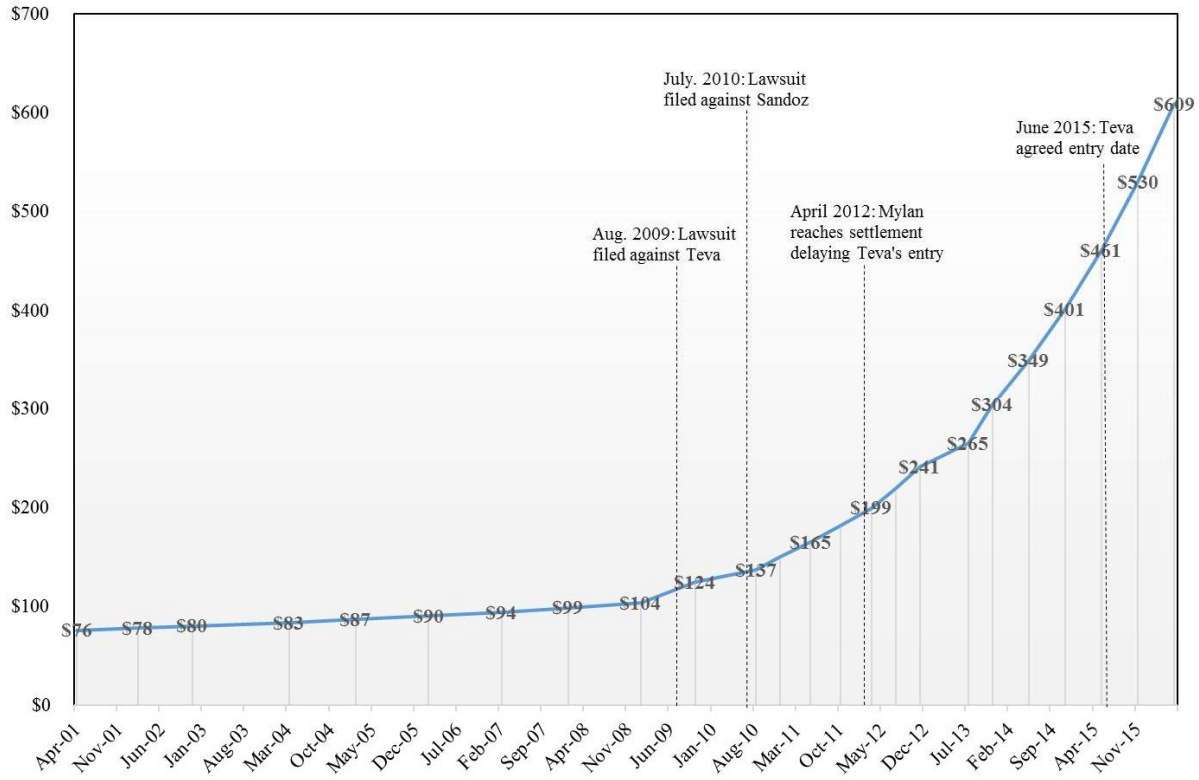
[61] Charles Duhigg, *Outcry Over EpiPen Prices Hasn't Made Them Lower*, N.Y. TIMES (June 4, 2017), https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html.

[62] Gretchen Morgenson, *EpiPen Price Rises Could Mean More Riches for Mylan Executives*, N.Y. TIMES (Sept. 1, 2016), https://www.nytimes.com/2016/09/04/business/at-mylan-lets-pretend-is-more-than-a-game.html.

[63] *Id*.

removed from the market. In May 2016, an EpiPen 2-Pak cost around $608. Today, an EpiPen 2-Pak costs over $650.

172. The chart below shows the exponential increase in wholesale EpiPen prices through 2016[64]:



173. The large price increases are not related to any corresponding or significant increase in manufacturing costs. The estimated cost of manufacturing for a two-pack of EpiPens is about $8.00. From 2012 to 2016, Mylan tripled the price of the EpiPen, even though its costs increased only about 15%.

64 *See* Wells Fargo Equity Research, *Mylan N.V.: MYL: Despite Recent Drop, We Remain on the Sidelines*, Feb. 19, 2016, at 18.

174. Upon information and belief, Mylan had implemented an incentive plan to motivate the company to increase profits[65]:

> Drug maker Mylan (MYL), under fire for sharply raising prices of a life-saving allergy treatment, two years ago urged executives to hit ambitious five-year sales and profit targets with a special incentive plan.
>
> If achieved, the special one-time award, offered to more than 100 "key employees," would mean tens of millions of dollars in bonuses for the executives of the Netherlands-based company.
>
> The plan's goal is to double Mylan's 2013 adjusted earnings per share of $2.89 to $6 by the end of 2018, an "ambitious" 16% compound annual growth rate, according to the company's 2014 proxy statement.
>
> Since the incentive plan was enacted, the cost of EpiPen two-packs negotiated by insurers and employers has risen from less than $400 to more than $600…. The Wall Street Journal reported Thursday on the incentive plan, which was also detailed last week by Business Insider. With a potential increase of $82 million to the top five executives, Mylan management might see EpiPen price hikes as a way to make the aggressive targets.
>
> [. . .]
>
> "When they thought they would have a revenue or profit shortfall somewhere else they decided to get more aggressive on EpiPen, because that is where they thought they would be able to raise some prices, make some more profit and make their targets," Ronny Gal, an analyst at Sanford C. Bernstein, told USA TODAY.

175. During the relevant time period, EpiPens were far cheaper outside of the United States. By way of example, the wholesale price for a 2-pack of EpiPens in the United States was

[65] Mike Snider, *EpiPen Maker Ties Bonuses to Profit Targets*, USA TODAY, (Sept. 1, 2016), http://www.usatoday.com/story/money/business/2016/09/01/epipen-maker-ties-bonuses-profittargets/89710582/.

more than $600, while the same 2-pack of EpiPens ranged from only about $100 in France to just over $200 in Germany.

176. In December 2016, Mylan introduced its own generic version of the EpiPen with a list price of $300 for a package of two devices. At $300, Mylan's generic is still sold at triple the 2007 price of EpiPen.

177. Mylan's generic is "a calculated maneuver. If Mylan is prepared to offer a $300 generic injector, made in the same factories with the same components, why doesn't it just sell the EpiPen for the lower price? The answer is all business and no medicine: Mylan can hang onto the market for doctors and patients who demand the trusted brand name, while cornering an incipient generic market."[66]

178. Although brand name EpiPen sales have dropped since the introduction of Mylan's authorized generic, Mylan still dominates the $2.5 billion EAI market. EpiPen and Mylan's authorized generic accounted for 72% of sales in 2019.

VI. DEFENDANTS'ACTIONS IMPACT INTERSTATE TRADE AND COMMERCE

179. At all material times, Defendants manufactured, promoted, distributed, and sold a substantial number of EpiPens in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

180. As described herein, during the Class Period, Mylan sold EpiPens throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District. Pfizer contributed to these sales as it manufactured EpiPens for Mylan.

---

[66] Elisabeth Rosenthal, *The Lesson of EpiPens: Why Drug Prices Spike, Again and Again*, N.Y. TIMES (Sept. 2, 2016), http://www.nytimes.com/2016/09/04/opinion/sunday/the-lesson-ofepipens-why-drug-prices-spike-again-and-again.html.

181. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

182. Defendants' conduct, including Mylan's marketing and sale of EpiPen has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

183. The anticompetitive conduct alleged in this Consolidated Fourth Amended Class Action Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiffs and Class Members of the benefits of free and open competition in the purchase of EAI within the United States.

184. Defendants' inflating, fixing, raising, maintaining, or artificially stabilizing EpiPen price, was intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

VII. MARKET POWER AND DEFINITION

185. The relevant geographic market is the United States, its territories and possessions, and the Commonwealth of Puerto Rico.

186. At all relevant times, Mylan had monopoly power in the market for EAIs because it had the power to maintain the price of EpiPen at supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as EpiPen.

187. At all relevant times, Mylan has consistently dominated the EAI drug device market with sales of the EpiPen and, later, the EpiPen and Mylan's authorized generic.

188. During the Class Period, EpiPen has dominated the EAI market. Mylan's 2010 Form 10-K states that the "principal market" for the company's specialty segment, which includes

EpiPen sales, is "pharmaceutical wholesalers and distributors, pharmacies and healthcare institutions primarily in the U.S." [67]

189. To the extent that Plaintiffs and Class Members may be required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is composed of EAIs, both brand and generic, in all forms and dosage strengths sold in the United States

190. Non-EAI drugs cannot be substituted automatically for EAIs by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to EAIs, and thus are not economic substitutes for, nor reasonably interchangeable with, EAIs. The FDA does not consider EAIs and non-EAI medications to be interchangeable.

191. Further, non-EAI products designed to treat anaphylaxis are not substitutes for EpiPen, its generic equivalents, or other EAIs, and their existence has not significantly constrained the pricing of EpiPen.

192. A small but significant, non-transitory price increase by Defendants to EpiPen would not have caused a significant loss of sales to other drugs or products used for the same purposes.

193. Mylan needed to control only EpiPen and other EAIs, and no other products, in order to maintain the price of EpiPen profitably at supra-competitive prices. Only the market entry of a competing EAI would render Mylan unable to profitably maintain its prices for EpiPen without losing substantial sales.

---

[67] Mylan Inc., 2010 Annual Report (Form 10-K) at 80 (Feb. 24, 2011).

194. Mylan itself has admitted that EAIs are a relevant product market, that the EpiPen dominated the market, and that for many years Mylan controlled the EAI market with close to a 100% market share. For example, on April 26, 2012, Mylan CFO John Sheehan boasted, "we are the market for anaphylactic shock with over 98% market share."[68] Again, on, August 1, 2013, Mylan told investors that EpiPen had a "93.3% market share."[69]

195. Mylan admitted that market factors affected the ability of competitors to enter the market, as noted by Mylan's CFO John Sheehan on a March 4, 2014 earnings call:

> 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 months.

196. At competitive price levels, EpiPen does not exhibit significant positive cross-price elasticity of demand with any product other than EAIs.

197. Mylan also sold branded EpiPen well in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

198. At all relevant times, there were high barriers to entry with respect to competition in the market for EAIs due to patent and/or other regulatory protections, and high costs of entry and expansion for competitors, some of which were created intentionally by Defendants.

199. According to the 2016 Orange Book, Defendants listed four patents related to epinephrine auto-injectors, all of which are set to expire in November 2025. Defendants' control

---

68 Transcript, Mylan Inc., Earnings Call (Apr. 26, 2012).

69 Presentation, Mylan Inc., *Mylan Investor Day: Seeing is Believing* (Aug. 1, 2013).

over these patents means that firms seeking entry with a generic auto-injector prior to 2025 can do so only by certifying, through the filing of a Paragraph IV certification with the FDA, that each patent is invalid or will not be infringed by a generic device.

200. A 2012 analyst report noted that Defendants "ha[ve] been taking steps on multiple fronts to stymie generics, including the introduction of a redesigned auto-injector in 2009 that offers some incremental safety features and carries additional IP protection."[70] In 2009 earnings call, Bresch "told investors that the company would be introducing a new version of EpiPen's auto-injector device, one with patent protection that would make it more difficult for a generic competitor to enter. The month that the company launched the improved product, Mylan boosted the list price of the drug by 20 percent." According to Jacob Sherkow, an associate professor at New York Law School, by revising its product, Mylan was "essentially wiping the slate clean–if any generic company wants to create a generic version, they're going to have to start a lawsuit."[71] The delivery device is an additional barrier to entry.

201. Defendants have maintained and exercised the power to exclude and restrict competition to EpiPen.

202. Defendants' monopoly power over EAIs can also be shown through circumstantial evidence, including a high share of the EAI market.

203. Mylan was also able to increase the wholesale acquisition cost for EpiPen throughout the relevant time period. As noted above, between 2007 and 2016, the EpiPen WAC

---

[70] *See* Susquehanna Financial Group, "Mylan, Inc.: A Good Growth Story that Should Have Legs," Mar. 14, 2012, at 12.

[71] Carolyn Y. Johnson & Catherine Ho, *How Mylan, the maker of EpiPen, became a virtual monopoly*, WASHINGTON POST (Aug. 26, 2016).

has increased by 500%. Despite Mylan's price increases, the EpiPen's market share remained stable.

204. Direct proof exists that Mylan possessed monopoly power over the price of EAIs. Such direct evidence includes, among other things, the abnormally high price-cost margins enjoyed by Mylan prior to entry of generic EpiPen and Mylan's ability to profitably maintain the price of EpiPen well above competitive levels.

205. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic EpiPens throughout the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

VIII. ANTITRUST IMPACT AND DAMAGES TO THE CLASS

206. Defendants' anticompetitive conduct had the following effects in the EAI market:

a. Generic entry of Teva's AB-rated generic EpiPen was substantially delayed;

b. Competition in the EAI market was reduced or eliminated;

c. Prices have been maintained at supra-competitive levels; and

d. United States purchasers have been deprived of the benefit of price competition in the EAI market.

207. As described herein, during the Class Period, Plaintiffs and Class Members directly purchased EpiPen from Mylan. Thus, the unlawful conduct of Defendants deprived Plaintiffs and Class Members of the benefits of competition that the antitrust laws were designed to ensure.

208. As a result of Defendants' anticompetitive conduct, Plaintiffs and Class members paid more for EpiPens than they otherwise would have and thus suffered substantial damages.

Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

209. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Defendants' EpiPen monopoly and limiting competition after entry of a generic or other EAI. Defendants' actions allowed them to maintain a monopoly and exclude competition in the EAI market.

210. Moreover, due to Defendants' misconduct, as alleged herein, other generic manufacturers were discouraged from and/or delayed in (a) developing and marketing generic versions of the EpiPen, and/or (b) challenging the validity or infringement of the EpiPen patents in court.

211. Defendants' exclusionary conduct has delayed competition and unlawfully enabled them to sell EpiPen without competition. But for the illegal conduct of Defendants, additional generics or other EAIs would have earlier captured market share.

212. As a result of Defendants' conduct, during the Class Period (defined herein), Plaintiffs and other Class Members directly purchased a substantial number of EpiPens and generic EpiPens. As a result of Defendants' illegal conduct, Plaintiffs and other Class Members paid, and will continue to pay, artificially inflated prices for those EpiPens and generic EpiPens. Plaintiffs and other Class Members paid prices for EpiPens that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) Class Members were deprived of the opportunity to purchase lower-priced generic EpiPens; and (b) Class Members paid artificially inflated prices for their EpiPens.

213. The prices that Mylan charged in the United States were inflated as a direct and foreseeable result of its anticompetitive conduct. As a consequence, direct purchasers of EpiPen have sustained injury to their business and property in the form of continuing overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

214. Thus, Defendants' unlawful conduct deprived Plaintiffs and other Class Members of the benefits of competition that the antitrust laws were designed to ensure.

215. But for Defendants' anticompetitive conduct, Plaintiffs and Class members would have paid less for EpiPen by: (a) substituting purchases of less-expensive EAIs for their purchases of more expensive brand EpiPen; (b) receiving discounts on their remaining brand EpiPen purchases; and/or (c) purchasing other EAIs or generic EpiPens at lower prices.

IX. TOLLING OF STATUTES OF LIMITATION

216. Plaintiffs incorporate and reallege all paragraphs in this Consolidated Fourth Amended Class Action Complaint as though fully set forth below.

217. At all times relevant to the Consolidated Fourth Amended Class Action Complaint, Defendants took active steps to conceal their unlawful activities, including the unlawful monopolization alleged herein. For example, and without limitation, Defendants concealed their conspiracy to exclude generic competition by: (a) asserting invalid patents against potential competitors and ultimately reaching unlawful settlements that to this date have been kept confidential and have operated to keep competitors from the market; and (b) filing citizen petitions with the FDA that were executed and timed solely to delay generic entry in the EAI market.

218. Plaintiffs and Class Members had no knowledge of the unlawful conduct alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until on

or about August 22, 2016, the date that Congress publicly announced an investigation into EpiPen pricing.

219. No information in the public domain was available to Plaintiffs and Class Members concerning Defendants' unlawful activities, including the combination or conspiracy alleged herein, before August 22, 2016, the date the public first learned of a Congressional investigation into Mylan's unlawful pricing practices. Prior to that date, Defendants had disclosed only incomplete and selective information to the public, which was insufficient for Plaintiffs and Class members to evaluate whether they had been harmed by Defendants' conduct.

220. For these reasons, the statute of limitations as to Plaintiffs' and Class Members' claims did not begin to run and has been tolled with respect to the claims that Plaintiffs and Class members have alleged in this Consolidated Fourth Amended Class Action Complaint.

221. In the alternative, the doctrine of fraudulent concealment tolls the statute of limitations on the claims asserted herein by Plaintiffs and Class Members. Plaintiffs and Class Members did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the conduct alleged herein, until on or about August 22, 2016, the date Congress publicly announced its investigation of EpiPen pricing.

222. Before August 22, 2016, Plaintiffs and Class Members were unaware of Defendants' unlawful conduct to monopolize the EAI market as disclosed in this Consolidated Fourth Amended Class Action Complaint and did not know before then that they were paying supra-competitive prices for EpiPens during the Class Period as a result of Defendants' anticompetitive conduct. Defendants provided no information, actual or constructive, to Plaintiffs and Class Members indicating they were being injured by Defendants' unlawful conduct. The Congressional investigation and information made public from it caused Plaintiffs and Class

Members to further investigate and inquire into the allegations described previously. Pharmaceutical antitrust claims are inherently complex, encompassing several areas of law; Plaintiffs and Class Members have been diligently researching their claims and investigating their damages since disclosure by the Congressional investigation.

223. The affirmative acts of Defendants alleged herein were wrongfully concealed and carried out in a manner that precluded detection.

224. By their very nature, Defendants' anticompetitive conspiracy and fraudulent scheme were inherently self-concealing. EpiPens and their generics are not exempt from federal antitrust laws, and Plaintiffs and Class members reasonably considered the EAI industry to be a competitive industry. Accordingly, a reasonable person under the circumstances would not have been alerted to begin to investigate the legitimacy of Defendants' EpiPen prices before August 22, 2016.

225. Plaintiffs and Class Members could not have discovered the unlawful activity described herein at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by Defendants to avoid detection of, and fraudulently conceal, their unlawful conduct as described in this Consolidated Fourth Amended Class Action Complaint.

226. Because the alleged unlawful conduct was self-concealing and affirmatively concealed by Defendants, Plaintiffs and Class Members had no knowledge of the alleged unlawful conduct, or of any facts or information that would have caused a reasonably diligent person to investigate, before August 22, 2016.

227. For these reasons, the statute of limitations applicable to Plaintiffs' and Class Members' claims was tolled and did not begin to run until August 22, 2016.

228. Plaintiffs and Class Members assert claims arising out of the conduct, transactions, and occurrences set out in the original Complaint filed by KPH on February 14, 2020, which tolled the statute of limitations for all direct purchaser Class Members. ECF No. 1.

229. Defendants are estopped from relying on any statute of limitations defense because their illegal, deceptive, and fraudulent practices as alleged herein, which are continuing violations, have created continuing and repeated injuries to Plaintiffs and Class members each time Plaintiffs and Class members have been or are overcharged for EpiPens.

230. Plaintiffs' and Class Members' claims accrue each time they are charged prices for the EpiPen and or generic EpiPen that have been inflated due to Defendants' anticompetitive conduct. Defendants engage in new and additional acts in violation of the antitrust laws each time they charge inflated prices for EpiPen and its authorized generic, and each sale of EpiPen or generic EpiPen at inflated prices inflicts a new injury on either Plaintiffs or Class Members. Plaintiffs and Class Members continue to purchase the EpiPen and generic EpiPen at inflated prices.

X. CLASS ACTION ALLEGATIONS

231. Pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and as representative of a class (the "Class") defined as follows:

> All persons or entities in the United States, its territories, possessions, and the Commonwealth of Puerto Rico, who purchased EpiPen or generic EpiPen directly from Mylan or Teva, for resale, at any time during the period from November 1, 2013 until the anticompetitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants and their officers, directors, management, employees, predecessors, subsidiaries, and affiliates, and all federal governmental entities.

232. Members of the Class are so numerous and/or geographically dispersed that joinder of all members is impracticable. While the exact number of Class members is unknown to

Plaintiffs, it is believed to number in the hundreds. The Class is readily identifiable from information and records in Defendants' possession.

233. Plaintiffs' claims are typical of the claims of the Class. Plaintiffs and other Class Members have all sustained damage in that, during the Class Period, they purchased EpiPen and/or generic EpiPen at artificially maintained, non-competitive prices, established by the Defendants' actions in connection with the violations alleged herein. Plaintiffs' interests are not antagonistic to the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

234. Plaintiffs will fairly and adequately protect the interests of all Class Members. Plaintiffs' interests are coincident with, and not antagonistic to, those of other Class Members. Additionally, Plaintiffs are represented by counsel experienced and competent in the prosecution of class action litigation and who have particular experience with class action litigation involving alleged violations of antitrust law.

235. Common questions of law and fact exist with respect to all Class Members and predominate over any questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire class, thereby determining damages with respect to the class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

236. The common legal and factual questions, which do not vary among Class Members include, but are not limited to, the following:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws and Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2;

b. whether a relevant market needs to be defined in this case in light of the existence of direct evidence of Defendants' power to exclude competition and charge supra-competitive prices for EpiPen;

c. if a relevant market needs to be defined, the definition of the relevant market for analyzing Defendants' monopoly power, and a determination of whether Defendants had monopoly power in the relevant market;

d. whether Defendants illegally maintained their monopoly power in the relevant market;

e. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiffs and the Class; and

f. if so, the appropriate measure of damages.

237. Class action treatment is the superior method to fairly and efficiently adjudicate this controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

238. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CAUSES OF ACTION

COUNT I

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

239. Plaintiffs incorporate and reallege all paragraphs in this Consolidated Fourth Amended Class Action Complaint as though fully set forth below.

240. Defendants engaged in an unlawful contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

241. During the relevant period, Defendants had monopoly power in the EAI market.

242. On April 26, 2012, Defendants entered into an illegal pay-for-delay agreement under which Teva was provided with substantial and valuable consideration in exchange for Teva's agreement to delay market entry of its AB-rated generic EpiPen until June 22, 2015, subject to FDA approval, and settle patent litigation relating to Teva's ANDA to manufacture and sell a generic EpiPen (after conclusion of a bench trial in that matter but before a verdict was entered).

243. The purpose and effect of Defendants' pay-for-delay agreement was: (1) to substantially delay generic entry of Teva's AB-rated generic EpiPen to lengthen the period in which Defendants could continue to charge supra-competitive prices for EpiPens; and (2) delay the date other generic manufacturers could enter the market.

244. While some of the alleged anticompetitive acts were performed by only one or a subset of Defendants, all were accomplished as part of Defendants' overarching conspiracy to restrain trade and delay entry of Teva's AB-rated generic EpiPen. Each Defendant played its respective role in that overarching conspiracy, as addressed in detail above, which collectively allowed the conspiracy to succeed and resulted in the unreasonable restraint of trade.

245. There is no valid procompetitive business justification for Defendants' anticompetitive conduct, and to the extent Defendants offer one, it is pre-textual and not cognizable. Any procompetitive benefits of Defendants' conduct do not outweigh the anticompetitive harms.

246. As the direct and foreseeable result of Defendants' agreements in restraint of trade, Plaintiffs and Class members paid artificially inflated prices for their EpiPen and/or generic EpiPen.

247. During the relevant period and as a result of Defendants' illegal conduct alleged herein, Plaintiffs and Class Members have been compelled to pay, and have paid, artificially inflated prices for EpiPens and AB-rated generic EpiPens. Plaintiffs and Class Members paid prices for such products that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs and Class Members were deprived of the opportunity to purchase lower priced generic versions of EpiPen instead of expensive brand-name EpiPen; and/or (2) the price of branded EpiPen was artificially inflated by Defendants' illegal conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

248. Plaintiffs and Class Members have been injured by Defendants' agreements in restraint of trade. Their injuries consist of paying higher prices for EpiPens and/or generic EpiPens than they would have in the absence of Defendants' violations of the Sherman Act. Plaintiffs' and Class Members' injuries did not end upon the introduction of generic EpiPens because Defendants' actions disrupted not only the trajectory of approvals and purchases of competitive products, but also the trajectory of pricing that, upon information and belief, continues at least until the present day.

COUNT II

VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2

249. Plaintiffs incorporate and reallege all paragraphs in this Consolidated Fourth Amended Class Action Complaint as though fully set forth below.

250. At all relevant times prior to December 2016, Defendants possessed monopoly power in the relevant market (the EAI market). That is, Defendants possessed the power to control and maintain prices and to exclude competitors from the relevant market.

251. Through their agreements with Teva, Defendants conspired to unlawfully maintain monopoly power in the relevant market by agreeing to delay market entry of Teva's AB-rated generic EpiPen.

252. The EpiPen ANDA Agreement (1) allocated to Defendants 100% of U.S. sales of EpiPen, (2) delayed the availability of Teva's AB-rated generic EpiPen until June 22, 2015, and (3) fixed Defendants' ability to continue to charge Plaintiffs and Class Members supra-competitive prices for EpiPens until at least June 2015.

253. The goal and effect of the EpiPen ANDA Agreement was to maintain and extend Defendants' monopoly power in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The EpiPen ANDA Agreement was intended to and did delay generic entry of Teva's AB-rated generic EpiPen and enabled Defendants to continue to charge supra-competitive prices for EpiPen without a substantial loss of sales.

254. Defendants knowingly and intentionally conspired to maintain and extend their monopoly power in the EAI market. Defendants intended for the EpiPen ANDA Agreement to maintain their monopoly power in the relevant market, injuring Plaintiffs and Class Members as a result.

255. Defendants each committed one or more overt acts in furtherance of their conspiracy to monopolize.

256. As the direct and foreseeable result of their misconduct, Defendants unlawfully maintained and extended their monopoly power, and Plaintiffs and Class Members were harmed and forced to pay overcharges as a result. Their injuries consist of paying higher prices for EpiPens and/or generic EpiPens than they would have in the absence of Defendants' violations of the Sherman Act. Plaintiffs' and Class Members' injuries did not end upon the introduction of generic

EpiPens because Defendants' actions disrupted not only the trajectory of approvals and purchases of competitive products, but also the trajectory of pricing that, upon information and belief, continues at least until the present day.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, pray for judgment against all Defendants, jointly and severally, as follows:

a. That the Court certify this lawsuit as a class action under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, direct that notice of this action, as provided by Fed. R. Civ. P. 23(b)(2) , be given to the Class, designate Plaintiffs as class representatives, and appoint Plaintiffs' counsel as Class counsel;

b. That the Court adjudge and decree that each Defendant violated Section 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2;

c. That the Court enter joint and several judgments against Defendants and in favor of Plaintiffs and the Class;

d. That Plaintiffs and the Class be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

e. That Plaintiffs and the Class be awarded reasonable attorneys' fees and costs as provided by the law; and

f. That the Court enter such other and further relief as the Court may deem just and proper.

XIII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs, individually and on behalf of the proposed Class, demand a trial by jury on any and all issues so triable.

XIV. DESIGNATION OF PLACE OF TRIAL

Pursuant to Local Rule 40.2, Plaintiffs hereby request Kansas City, Kansas as the place for trial.

Respectfully submitted,

Dated: September 21, 2021

/s/ *Thomas P. Cartmell*
Thomas P. Cartmell, KS #17020
Eric D. Barton, KS #1650
Tyler W. Hudson, KS #20293
WAGSTAFF & CARTMELL LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
Telephone: (816) 701-1100
Facsimile: (816) 532-232
tcartmell@wcllp.com
ebarton@wcllp.com
thudson@wcllp.com

Michael L. Roberts (admitted *pro hac vice*)
Erich P. Schork (admitted *pro hac vice*)
Sarah E. DeLoach (admitted *pro hac vice*)
ROBERTS LAW FIRM, P.A.
20 Rahling Circle
Little Rock, AR 72223
Telephone: (501) 821-5575
Facsimile: (501) 821-4474
mikeroberts@robertslawfirm.us
erichschork@robertslawfirm.us
sarahdeloach@robertslawfirm.us

Dianne M. Nast (*admitted pro hac vice*)
NASTLAW LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107
Telephone: (215) 923-9300
Facsimile: (215) 923-9302
dnast@nastlaw.com

Attorneys for Plaintiffs KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. and FWK Holdings, LLC

Norman E. Siegel (D. Kan. # 70354)
Rachel E. Schwartz (KS Bar # 21782)
STUEVE SIEGEL HANSON LLP
460 Nichols Road, Suite 200
Kansas City, Missouri 64112
Telephone: (816) 714-7100

Facsimile: (816) 714-7101
siegel@stuevesiegel.com
schwartz@stuevesiegel.com

Linda P. Nussbaum (admitted *pro hac vice*)
Bart D. Cohen (*pro hac vice* forthcoming)
NUSSBAUM LAW GROUP, P.C.
1211 Avenue of the Americas, 40th Floor
New York, NY 10036
Telephone: (917) 438-9102
lnussbaum@nussbaumpc.com
bcohen@nussbaumpc.com

Joseph H. Meltzer (*pro hac vice* forthcoming)
Terence S. Ziegler (*pro hac vice* forthcoming)
Ethan J. Barlieb (*pro hac vice* forthcoming)
Jordan E. Jacobson (*pro hac vice* forthcoming)
KESSLER TOPAZ MELTZER & CHECK, LLP
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
jmeltzer@ktmc.com
tziegler@ktmc.com
ebarlieb@ktmc.com
jjacobson@ktmc.com

Attorneys for César Castillo, LLC