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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ORANGE

THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Orange County District Attorney Tony Rackauckas,

Plaintiff,

vs.

ABBOTT LABORATORIES;
ABBVIE INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
BARR PHARMACEUTICALS, INC.;
DURAMED PHARMACEUTICALS, INC.;
DURAMED PHARMACEUTICALS SALES CORP.; and
DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

Case No. 30-2016-00879117-CU-BT-CXC

Judge Kim G. Dunning
CX104

COMPLAINT FOR VIOLATIONS OF CALIFORNIA UNFAIR COMPETITION LAW, SEEKING RESTITUTION, CIVIL PENALTIES AND INJUNCTIVE RELIEF

COMPLAINT

Plaintiff, the People of the State of California ("Plaintiff" or "the People"), by and through Tony Rackauckas, District Attorney for the County of Orange ("District Attorney"), alleges the following, on information and belief:

I. INTRODUCTION

1. This is an action brought by Tony Rackauckas, District Attorney of the County of Orange, for violations of California Business and Professions Code sections 17200 et seq., the Unfair Competition Law ("UCL"), involving the purchases of, and reimbursements for, the prescription drug Niaspan occurring in California, including California Niaspan users, their insurers, public healthcare providers and other government payors. Niaspan is a time-released dosage of the vitamin niacin and is used to treat high cholesterol. The defendants are Abbott Laboratories, AbbVie Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, Inc., Duramed Pharmaceuticals, Inc., Duramed Pharmaceuticals Sales Corp. and Does 1 through 100. This is a law enforcement action which primarily seeks to protect the public safety and welfare, brought by a governmental unit in the exercise of and to enforce its police power. *City & Cnty. of San Francisco v. PG & E Corp.*, 433 F.3d 1115, 1124-25 (9th Cir. 2006); *California v. Purdue Pharma L.P.* (C.D. Cal., Nov. 12, 2014, No. SACV 14-1080-JLS DFM) 2014 WL 6065907, *4; *In re General Motors LLC Ignition Switch Litigation* (S.D.N.Y. 2014) 69 F.Supp.3d 404, 416.

2. This case is based on several simple and provable facts: the brand name manufacturers of Niaspan entered into agreements with generic drug manufacturers wherein the brand name manufacturers provided substantial value to the generic manufacturers in exchange for the generic manufacturers agreeing not to bring generic versions of Niaspan to market in the United States. This agreement was successfully carried out by the defendants, and resulted in California users, their insurers, public healthcare providers and other government payors paying substantially higher prices for Niaspan than they would have if the generic version had been available.

3. As a direct and proximate result of their unlawful scheme to keep generic versions of Niaspan off the market, and in violation of California's consumer protection laws, Defendants: (a) illegally maintained monopoly power in the market for Niaspan in the United States from 2005

through March 2014, at the earliest, and sold more than $6.7 billion of Niaspan or generic Niaspan from 2005 until at least March of 2014 at supracompetitive prices; (b) illegally maintained the price of Niaspan at supracompetitive levels; and (c) caused California users, their insurers, public healthcare providers and other government payors to overpay millions of dollars by depriving them of the benefits of access to less expensive generic versions of Niaspan.

II. PLAINTIFF'S AUTHORITY

4. Tony Rackauckas, District Attorney of the County of Orange, acting to protect the public as consumers from unlawful and unfair business practices, brings this action in the public interest in the name of the People of the State of California pursuant to section 17200 of the California Business and Professions Code. Plaintiff, by this action, seeks to enjoin Defendants from engaging in the unlawful and unfair business practices alleged herein, and seeks civil penalties and restitution for the Defendants' violations of the above statute.

III. DEFENDANTS

5. Defendant Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott purchased Kos Pharmaceuticals, Inc. in a tender offer transaction in 2006. On or about on January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie, Inc. At all relevant times, Defendant Abbott sold Niaspan and engaged in the conduct challenged in this case and attributed to Abbott, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

6. Defendant AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. As of January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie. At all relevant times, Defendant AbbVie sold Niaspan and engaged in the conduct challenged in this case and attributed to AbbVie, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

7. Defendant Barr Pharmaceuticals, Inc. ("Barr") is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Prior to 2004, Barr was known as Barr Laboratories, Inc. In 2008, Barr became a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva"). At all relevant times, Defendant Barr engaged in the conduct challenged in this case and attributed to Barr, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

8. Defendant Duramed Pharmaceuticals, Inc. ("Duramed") is a corporation with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed is now known as Teva Women's Health, Inc. At all relevant times, Defendant Duramed engaged in the conduct challenged in this case and attributed to Duramed, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

9. Defendant Duramed Pharmaceuticals Sales Corp. ("DPSC") is a corporation with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva and along with Duramed, became known as Teva Women's Health, Inc. At all relevant times, Defendant DPSC engaged in the conduct challenged in this case and attributed to DPSC, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

10. Defendant Teva Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva has securities listed on the New York Stock Exchange and upon information and belief has employees conducting business in California. Teva is a leading manufacturer of generic drugs, and it is one of the largest sellers of generic drugs in the United States, including in the State of California. Teva purchased Barr in 2008, and Barr is now a wholly-owned subsidiary of Teva. Teva has a facility in this District. At all relevant times, Defendant Teva engaged

in the conduct challenged in this case and attributed to Teva, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith. On September 20, 2013, Teva announced its launch of a generic equivalent of Niaspan, pursuant to the terms of the agreement that was originally reached by Kos Pharmaceuticals, Inc. and Barr in 2005, as discussed below.

11. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva USA is a wholly-owned subsidiary of Teva. Teva USA manufactures and/or distributes generic drugs for sale and use throughout the United States and in Orange County at the direction, under the control, and for the direct benefit of Defendant Teva. At all relevant times, Defendant Teva USA engaged in the conduct challenged in this case and attributed to Teva USA, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

12. Although not named as a Defendant, Kos Pharmaceuticals, Inc. ("Kos") was one of the initiators of the unlawful agreement described in this Complaint. Kos was a corporation organized under the laws of the state of Florida, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos was merged into and became a part of Abbott, which became the successor to all of Kos' unlawful conduct described in this Complaint.

13. Although not named as a Defendant, Kos Life Sciences, Inc. is a subsidiary of Kos, and was one of the initiators of the unlawful agreement described in this Complaint. Kos Life Sciences, Inc. was a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. Kos Life Sciences, Inc. was a wholly-owned subsidiary of Kos. In 2006, when Kos was merged into Abbott, Kos Life Sciences, Inc. became a Division of Abbott Laboratories, and Abbott became the successor to all of Kos Life Sciences, Inc.'s unlawful conduct described in this Complaint.

14. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to CCP § 474. Plaintiff will amend this Complaint to

show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

15. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the illegal restraint of trade alleged herein, and were authorized, ordered, and/or performed by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

16. Although not named as Defendants, various other individuals and entities may have participated as co-conspirators with Defendants, and may have engaged in conduct and made statements in furtherance of the conspiracy.

IV. JURISDICTION AND VENUE

17. This Court has jurisdiction over this matter pursuant to the California Constitution, Article XI, Section 10 and California Code of Civil Procedure ("CCP") section 410.10 because the Defendants transact and have transacted business in California, and the violations of California law complained of herein resulted in damages to consumers of Niaspan in California, including in the County of Orange.

18. Venue is proper in the County of Orange, California, pursuant to CCP section 395, because the Defendants transact and have transacted business in this County, and some of the acts complained of have occurred in this venue.

V. REGULATORY BACKGROUND

A. Generic Drugs Benefit Purchasers

19. Generic competition allows purchasers at all levels of the pharmaceutical supply chain to purchase both the brand name drug and its generic equivalents at a reduced price. Generic competition to a single branded drug can provide billions of dollars in savings to consumers, insurers, pharmacies, and other drug purchasers.

20. Generics that meet all of the requirements for approval are assigned an "AB" rating by the FDA. The AB rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter. All states permit pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has said that the prescription for the brand name product must be dispensed as written. When acting as a reimbursement agent (for example, through Medicaid), most states require such substitution.

21. Until a generic manufacturer enters the market, the brand name manufacturer maintains a pure monopoly, and can charge monopoly prices without a material loss in sales volume because the drug faces no competition. It is widely acknowledged that a monopolist's profit - maximizing price exceeds the price that would prevail in a competitive market. With respect to the market for branded pharmaceutical drugs and their AB-rated generic equivalents, the monopoly price is typically far in excess of the competitive price. Brand name drug manufacturers therefore have a strong interest in seeking to restrain generic competition.

22. Third-party payors (such as health insurance plans) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. And many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. AB-rated generic drugs therefore capture a significant share of their branded counterparts' sales, causing a significant reduction in the branded drug's unit and dollar sales.

23. The first AB-rated generic drug is typically priced significantly below its branded counterpart. As more AB-rated generics enter the market, the brand and generic drug prices usually continue to decline as the generics compete with one another and the brand name drug.

24. The first generic equivalent to reach the market often captures 80% or more of the market within the first six months. Within one year of market entry, the generic often accounts for 90% of the branded drug's unit sales and sells for 15% of the price of the brand name drug.

B. The FDA Approval Process

25. Under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), manufacturers who seek to market a new drug must apply for FDA approval to sell the drug by filing a New Drug

Application, or NDA. 21 U.S.C. §§ 301-392. NDAs must include specific data concerning the safety and effectiveness of the drug and identify applicable patents. *Id.* at §§ 355(a) & (b).

26. When the FDA approves a brand manufacturer's NDA, the brand name manufacturer lists any patents it contends apply to the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). The FDA performs a ministerial duty in listing these patents, and does not confirm the accuracy of the information supplied by the brand manufacturer. After the NDA is approved, the brand manufacturer may list additional patents relating to the drug in the Orange Book.

C. The Government Encourages and Facilitates the Approval of Generic Drugs Through the Hatch-Waxman Amendments

27. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), known as the Hatch-Waxman Amendments.

28. The Hatch-Waxman Amendments simplify the regulatory hurdles that generic manufacturers have to clear to enter the market. Instead of filing a lengthy and costly NDA, the Hatch-Waxman Amendments allow generic manufacturers to seek FDA approval on an expedited basis by filing an Abbreviated New Drug Application, or ANDA.

29. If an ANDA applicant shows that the generic drug is "bioequivalent" to the brand name drug—that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug—then the ANDA may rely on the scientific safety and effectiveness findings included in the brand name drug manufacturer's original NDA. 21 U.S.C. § 355(j)(2)(A). The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the Act's requirements. 21 U.S.C. § 355((j)(4). The streamlined approval process under the Hatch-Waxman Amendments makes it easier for manufacturers to bring competing generic products to the market.

30. While Hatch-Waxman seeks to facilitate generic competition, the brand name manufacturer retains the right to enforce any patents associated with the drug. To gain regulatory approval, an ANDA application must also certify that the generic drug will not infringe the brand

name drug's patents listed in the Orange Book, because either: (i) no patents exist on the brand name product; (ii) the patents have expired; (iii) the patents will expire by the time the generic product comes to market; or (iv) the patents are invalid or will not be infringed by the sale of the generic product. See 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). The last certification, that the patents are invalid or not infringed, is known as a "Paragraph IV certification."

31. When a generic manufacturer files a Paragraph IV certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, it must promptly give notice of its certification to both the brand manufacturer and the owner of the patent. If the brand manufacturer files a patent infringement lawsuit against the ANDA filer within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) 30 months or (b) a court ruling that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). During the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval, but cannot authorize the generic manufacturer to market its drug before the 30-month stay expires or a court rules on invalidity and infringement.

32. Congress also created incentives for drug manufacturers to seek approval of generic alternatives to branded drugs and challenge weak patents. The Hatch-Waxman Amendments grant a 180-day period of market exclusivity to the first ANDA applicant to file a substantially complete ANDA containing a Paragraph IV certification. During the 180-day exclusivity period the first filer enjoys temporary freedom from competition from other generic versions of the drug, and is able to sell the generic for a higher price than when multiple generics enter the market. The brand name manufacturer may, however, market its own generic equivalent of the brand name drug (known as an "authorized generic") during the 180-day period.

33. The first-filed generic manufacturer can forfeit its right to the 180-day period of exclusivity. This can occur, for example, if the first-filer fails to market its product under certain circumstances or fails to receive tentative approval of its ANDA from the FDA within 30 months of filing the ANDA, unless the failure is caused by a change in or review of the requirements for approval of the ANDA.

34. When, as in this case, multiple generic companies file ANDAs with Paragraph IV certifications on the same day, each company is entitled to launch during the 180 day period, sharing exclusivity. See, Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day, 68 Fed. Reg. 45252, 45255 (Aug. 1, 2003). This results in the loss of the usual "first filer" advantage.

D. Some Pharmaceutical Manufacturers Misuse the Regulatory Structure

35. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

36. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, brand name manufacturers have also developed a practice of entering into "settlements" in which the brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. Initially these agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, Congressional investigations, and class action lawsuits, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

37. The first generic filer's agreement to delay marketing its drug may also prevent other manufacturers of generics from bringing their own products to market. If the first-filed generic manufacturer is eligible for 180-days of marketing exclusivity, no other generic manufacturer can enter the market until the end of the exclusivity period. This "bottlenecking" tactic is known as exclusivity "parking."

E. Agreements Not to Compete Between the Brand's Authorized Generic and the First-Filing Generic's Product

38. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an authorized generic is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Teva has traditionally marketed its authorized generic products in-house, through its wholly-owned subsidiary Roxane Laboratories, Inc. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

39. In its recent study, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission ("FTC") found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because: (a) the authorized generic takes a large share of unit sales away from the first filer; and (b) the presence of an additional generic in the market causes prices to decrease.

40. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as California benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

41. Given the significant negative effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has

tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers of the lower prices resulting from two forms of competition: (a) among the branded and the generic products; and (b) between the generic products.

42. Agreements not to compete with an authorized generic can take many forms. According to the FTC Study, one such form includes agreements like the Agreement here whereby the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized generic product. As confirmed by the FTC, the result is the same as if the brand agreed not to launch any authorized generic: no competition between an authorized generic and the first-filing generic's product for a period of time.

VI. FACTS

A. Niaspan Accounts For the Vast Majority of Kos' Sales Revenues

43. Niacin, the active ingredient in Niaspan, is Vitamin B-3. It was discovered in the late 1800s, appears naturally in many foods, and started being sold as a dietary supplement in the United States no later than the 1930s. In proper dosages, niacin has lipid-lowering properties. Niacin reduces LDL cholesterol (the so-called "bad cholesterol") and triglycerides, while also raising levels of HDL cholesterol (the so-called "good" cholesterol) in patients. For that reason, niacin has become a therapy to treat mixed lipid disorders. However, at high levels, niacin causes a patient's skin to flush with redness, and it may cause liver toxicity.

44. In the 1990s, Kos set out to develop a time-release version of niacin, which could avoid the side effects associated with high dosages of niacin, and which could be marketed as a once-a-day therapy for patients who needed treatment for cholesterol levels. Eventually, Kos developed Niaspan, a time-release version of niacin, which it intended to market as a brand-name prescription drug. Importantly, Kos did not claim to have discovered that niacin reduces cholesterol (that was documented in the 1950s), and was not the first company to make a sustained release niacin formulation. Kos simply created a formulation that had a release rate that helped minimize or avoid certain side effects.

45. Kos was unable to patent the active ingredient in Niaspan under a compound patent, because niacin was not an innovative chemical compound. However, Kos sought and eventually received a series of patents to cover the formulation and method-of-use for Niaspan. Those patents were as follows:

Patent No. 6,080,428 (the '428 Patent)
Patent No. 6,129,930 (the '930 Patent)
Patent No. 6,406,715 (the '715 Patent)
Patent No. 6,676,967 (the '967 Patent)
Patent No. 6,746,691 (the '691 Patent)

46. In addition, Kos purchased Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

47. Kos filed an NDA with respect to Niaspan. On July 28, 1997, Kos received FDA approval to market Niaspan for the treatment of mixed lipid disorders.

48. Over time, Kos submitted the above-listed patents to the FDA for listing in the Orange Book, and the FDA listed them in the Orange Book.

49. In September of 1997, Kos went to market with Niaspan, eventually selling Niaspan in dosages of 500 mg, 750 mg, and 1000 mg (unless indicated otherwise, as used herein, "Niaspan" refers to all dosages of the drug). Niaspan was the only once-a-day prescription formulation of extended release niacin available for treating mixed lipid disorders. Because of its unique position, doctors prescribed Niaspan often, and the drug quickly became a multi-million dollar seller.

50. In the early years, nearly all of Kos' sales revenue was derived from sales of Niaspan, because Kos had no other significant drugs in its portfolio. Kos began to sell other drugs, but Niaspan always accounted for a substantial portion of Kos' sales revenues. Specifically, in those early years:

a. In 2001, Kos sold $87 million of Niaspan, which accounted for 100% of the company's sales revenue;

b. In 2002, Kos sold $146 million of Niaspan, which accounted for 84% of the company's sales revenue;

c. In 2003, Kos sold $226 million of Niaspan, which accounted for 77% of the company's sales revenue;

d. In 2004, Kos sold $319 million of Niaspan, which accounted for 64% of the company's sales revenue; and

e. In 2005, Kos sold $435 million of Niaspan, which accounted for 57% of the company's sales revenue.

51. In the early part of the 2000s, Kos had market power with respect to pricing Niaspan. Indeed, on several occasions during those early years, Kos reported that it was able to raise prices on Niaspan (even though costs were not increasing) while simultaneously increasing its sales volumes on the drug.

B. Barr Seeks FDA Approval to Market an AB-Rated Generic Bioequivalent to Niaspan, And Kos Views Barr as a Competitive Threat

52. On October 2, 2001, after conducting extensive research and analysis regarding the patents that Kos had registered, after conducting extensive legal due diligence concerning potential infringement or invalidity of Kos's patents, and after investing more than $2.3 million on that research, Barr submitted ANDA 76-250 to the FDA, seeking approval to market a generic equivalent of the 1000 mg dosage of Niaspan.

53. On January 15, 2002, Barr sent a Paragraph IV Certification with respect to the listed patents covering Niaspan in a 1000 mg dosage. In that Paragraph IV Certification, Barr stated that its proposed generic equivalent to Niaspan would not infringe any of Kos' patents then listed in the Orange Book, that Kos' patents were invalid, and/or that Kos' patents were unenforceable. Barr was the only company to file such a certification at that time. That Paragraph IV Certification marked the beginning of Barr's efforts to bring a generic equivalent of Niaspan to market. As the first ANDA filer, Barr would be entitled to a 180-day period of market exclusivity once it received final approval from the FDA to enter the market.

54. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring a less expensive generic equivalent of Niaspan to market. On March 4, 2002, Kos sued Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-1683), alleging that Barr's Paragraph IV certification infringed upon the '428 Patent and the '930 Patent with respect to the 1000 mg dosage of Niaspan. By operation of law, the filing of that lawsuit triggered a 30-month stay under the Hatch-Waxman Act that prohibited the FDA from granting Barr Final Approval to launch a generic equivalent of Niaspan.

55. In the months that followed, Kos filed two more patent infringement lawsuits against Barr with respect to patents relating to Niaspan:

a. On August 13, 2002, Kos filed a patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-6409), this time alleging that Barr had infringed the '428 Patent and '930 Patent by filing ANDA 76-378 (with an accompanying Paragraph IV Certification) with respect to the 500 mg and 750 mg dosages of Niaspan; and

b. On November 12, 2002, Kos filed a patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-8995), this time alleging that Barr had infringed the '715 Patent by submitting a Supplemental Paragraph IV Certification (dated September 30, 2002) regarding Niaspan.

56. These lawsuits were all consolidated into one proceeding. Under the law as it existed at that time, each of those lawsuits triggered a new 30-month stay under the Hatch-Waxman Act, and the last of those 30-month stays began to run on September 30, 2002 (the date of Barr's Supplemental Paragraph IV Certification). Thus, the FDA was stayed from granting Barr Final Approval for marketing any generic equivalent of Niaspan until March 31, 2005.

57. On March 26, 2004, Kos filed a fourth patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 04-CV-1683), this time alleging that Barr had infringed the '967 Patent by filing Paragraph IV Certifications with respect to that Niaspan patent.

58. That fourth case was consolidated with the first three cases, into one single proceeding. In the consolidated proceeding, Barr filed Counterclaims against Kos, seeking Declaratory Judgments that Barr's Paragraph IV Certifications did not infringe any of the relevant patents held by Kos (specifically naming the '145 Patent, the '181 Patent, the '428 Patent, the '715 Patent and the '930 Patent). Barr's Counterclaims also sought rulings that those patents were invalid or otherwise unenforceable.

59. On September 3, 2004, Barr filed an action against Kos in the United States District Court for the Southern District of New York (docketed as 04-CV-7086), seeking a Declaratory Judgment that Barr was not infringing the '691 Patent and/or that the '691 Patent was invalid or otherwise unenforceable. This fifth lawsuit was also consolidated with the other pending patent infringement actions in New York.

60. In these consolidated proceedings, Barr contended that Kos' patents were invalid or otherwise unenforceable, and/or not infringed.

61. While the patent suits were pending in New York, and while the 30-month stay was still in place from the first three lawsuits, the FDA gave Barr Tentative Approval to proceed to market with its generic equivalent of Niaspan. Barr received tentative approval to market its 1000 mg generic equivalent of Niaspan on May 9, 2003 and received tentative approval to market its 500 mg and 750 mg generic equivalents of Niaspan on June 13, 2003. Barr expected to receive final approval from the FDA shortly after the last of the 30-month stays expired (that is, shortly after March 30, 2005). Indeed, Barr stated, in its filings in the consolidated proceedings, that it would launch a generic product as soon as it received final FDA approval permitting it to do so.

62. The patent lawsuits in New York continued for more than two years without any substantive rulings on the merits of the patent claims. There were no claims construction rulings and no summary judgment rulings. On December 3, 2004, the Court scheduled a Trial for the consolidated cases for January of 2006.

C. Barr Is Ready to Launch a Generic Equivalent of Niaspan At-Risk in The Spring of 2005

63. As 2004 was drawing to a close, Barr was preparing to launch its generic equivalent of Niaspan shortly after the 30-month stay expired, but before the patent litigation was resolved. This is known as an "At-Risk" launch. By the Spring of 2005, Barr was ready, willing, and able to launch its generic equivalent to Niaspan as soon as the FDA approved Barr's ANDA.

64. Barr's At-Risk launch would have brought a generic equivalent of Niaspan to market in the Spring of 2005 without regard to the expiration dates on any of Kos' patents (as listed in ¶ 41, above). Kos recognized Barr's At-Risk launch as a real competitive threat and acted swiftly in response.

65. First, Kos began preparing to launch its own authorized generic version of Niaspan, which would have deprived Barr of 180 days of exclusivity as the sole generic on the market, and which would have replaced some of Kos's lost brand revenues with those from authorized generic purchases. Kos began manufacturing its authorized generic version of Niaspan so that it would have inventory on hand to sell as soon as Barr launched. By the end of the first quarter of 2005, Kos had accumulated more than $1.3 million in inventory for its authorized generic launch. Kos was prepared

to launch -- and would have launched -- an authorized generic version of Niaspan as early as Spring 2005, if Barr had launched its generic equivalent of Niaspan At-Risk.

66. Second, on March 7, 2005, Kos filed papers with the New York Court in the patent litigation, applying for a preliminary injunction to prohibit Barr from continuing with its At-Risk launch of a generic equivalent of Niaspan. The Court held a hearing on Kos' application for a preliminary injunction on March 18, 2005. At the time of the March 18th Hearing on Kos' Application for a Preliminary Injunction, Barr was ready to launch its generic equivalent of Niaspan, At-Risk. Barr was accumulating inventory that it would need to fill orders for its generic product as soon as the launch occurred. Barr was only waiting on the FDA to issue Final Approval, which Barr expected to receive in April upon the expiration of the 30-month stay.

D. Kos and Barr Enter the Reverse Payment Agreement, Agreeing That Barr Will Not Launch A Generic Competitor to Niaspan For More Than Eight Years

67. On March 30, 2005 -- before the New York Court ruled on Kos' application for a preliminary injunction -- Kos and Barr announced that they had settled the patent litigation, and they asked the court to postpone any ruling on that application, so that they could formalize their settlement. The Judge agreed, and issued a Conditional Order of Discontinuance on March 30, 2005.

68. The fact that Barr was ready to launch At-Risk in April of 2005 led Kos to settle the patent litigation in March of 2005. Niaspan was important to Kos' viability, the prospect of an At-Risk launch by Barr posed a great threat to the pricing of Niaspan, and Kos knew there was a substantial risk that it would lose the patent litigation. Kos therefore decided to pay Barr to delay entering the market with generic Niaspan, thereby preserving Kos's ability to continue selling a large volume of Niaspan at supracompetitive prices.

69. Thus, Kos and Barr entered into the Reverse Payment Agreement: Kos agreed to make unlawful payments to Barr over a period of eight years, and Barr unlawfully agreed to refrain from launching a generic equivalent of Niaspan until September of 2013. That Agreement preserved Niaspan's dominant position in the market, while sharing some of the supracompetitive profits that were the result of that dominant position.

70. As part of the Reverse Payment Agreement, Kos and Barr executed three contracts that facilitated and helped effectuate their unlawful Agreement. Those three contracts were as follows:

a. **Settlement and License Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license of all of the patents arguably covering Niaspan, on the condition that Barr would not bring a generic equivalent of Niaspan to market until September 20, 2013 (or such earlier time as may be required to preserve Barr's right to market a generic exclusively for 180 days). The license also permitted Barr to launch a generic equivalent of another drug, Advicor (a drug that combined Niaspan with a Statin, a separate chemical entity that tended to lower LDL cholesterol in patients), and Barr agreed not to launch that generic until September 20, 2013. (Advicor had not been part of their patent litigation up until then.) For a period of years after Barr began selling its generic equivalents of Niaspan and Advicor, for every unit of those generics that Barr would sell, Barr agreed to pay a percentage of its supracompetitive profits on Niaspan to Kos. Barr explicitly agreed that it would not launch a generic equivalent of Niaspan until the date provided in the license (scheduled for September 20, 2013). Kos also agreed that it would not launch an authorized generic version of Niaspan, transferring a large payment to Barr by enabling it to charge higher prices for a larger volume of sales than it could have in the presence of an authorized generic.

b. **Co-Promotion Agreement.** For as long as Barr kept its generic equivalent of Niaspan and Advicor off the market, as provided in the Settlement and Licensing Agreement, Kos agreed to pay Barr (through Duramed and DPSC, two Barr subsidiaries), a royalty on all of Kos' sales of Niaspan and Advicor. Barr, Duramed and DPSC agreed to promote Niaspan and Advicor to obstetricians, gynecologists and other doctors specializing in women's health. The royalty that Kos paid to Barr was based upon overall sales of Niaspan and Advicor, regardless of whether the sales were made by Barr's sales force.

c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA-approved manufacturing processes for Niaspan and Advicor. Kos (and Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacture Niaspan and Advicor. Barr agreed to serve as a ready back-up supplier to Kos for those products, and agreed to sell them to Kos at an agreed-upon contract price.

71. The Reverse Payment Agreement included two other notable provisions:

a. Kos and Barr agreed to do all things reasonably necessary to further the intent and purposes of the transactions contemplated by the Agreement.

b. Kos and Barr agreed that either company could transfer its rights and obligations to a successor entity through a merger or other corporate takeover.

72. On April 12, 2005, the New York court dismissed all of the patent infringement cases that were pending between Barr and Kos regarding Niaspan.

73. On April 26, 2005, the FDA gave Kos final approval for its generic equivalent of Niaspan, in all doses.

74. In the Spring of 2005, Barr disposed of the inventory it had accumulated to be ready for its At-Risk generic launch, and Barr took an inventory write-down in connection with its decision not to launch At-Risk in April of 2005. Also, in the Spring of 2005, Kos took a write-down for its inventory of an authorized generic version of Niaspan. Kos had accumulated that inventory through the First Quarter of 2005, on the expectation that Kos would need to begin selling a generic product as soon as Barr launched At-Risk.

75. Under the Reverse Payment Agreement, Kos paid Barr to not launch until 2013. The payments took at least the following forms:

a. An agreement by Kos not to enter the market with an authorized generic version of Niaspan during Barr's 180-day exclusivity period;

b. An agreement by Kos not to enter the market with an authorized generic version of Advicor during the period that Barr is marketing generic Advicor;

c. A lump sum payment, which was disguised as a "stand-by" payment to compensate Barr for being ready to manufacture Niaspan under the License and Manufacturing Agreement (when in fact Kos did not need Barr to stand-by, and the stand-by payment far exceeded the value that Barr provided to Kos by being ready to manufacture and supply Niaspan);

d. Quarterly payments, which were disguised as payments to compensate Barr for remaining ready to manufacture Niaspan under the License and Manufacturing Agreement (when in fact Kos did not need Barr to stand-by, and the quarterly payments far exceeded the value that Barr provided by remaining ready to manufacture and supply Niaspan); and

e. Quarterly Royalty Payments, which were disguised as compensation for Barr's work under the Co-Promotion Agreement (when in fact those payments far exceeded the value of the promotion efforts that Barr provided).

76. All of these benefits had substantial value to Barr, and are compensation that it could not have obtained even if it had litigated and won the patent case. Kos agreed to pay Barr to delay entry into the market, and these payments caused Barr to agree to stay out of the market longer than it otherwise would have done.

77. But for the parties' ongoing adherence to their Reverse Payment Agreement, generic competition for Niaspan would have occurred earlier and prices for Niaspan (both generic and branded) would have been lower.

78. If Barr had launched a generic equivalent of Niaspan -- either in an At-Risk launch or at any time before September 20, 2013 -- the generic equivalent would have sold at lower prices than the prices at which Kos was selling the brand name version of Niaspan. Purchasers would have paid lower prices -- on both brand name Niaspan and on the generic equivalent of Niaspan -- than they otherwise paid.

79. If Kos had launched its authorized generic equivalent of Niaspan, prices would have dropped even lower. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a branded product. The Reverse Payment Agreement prevented that generic competition from occurring.

80. If Barr had launched At-Risk and/or had agreed to an entry date earlier than September 2013, other generic manufacturers would have been able to launch their own generic equivalents of Niaspan after 180 days had passed following Barr's At-Risk launch. That is, as the first filer, Barr had a 180-day period in which it would be the exclusive outside generic manufacturer of a Niaspan equivalent, and that 180-day exclusivity period would not begin to run until 180 days after Barr launched its product. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent -- and succeeded in preventing -- other generic manufacturers from launching until 2014.

81. Hence, the purpose and effect of the agreement between Kos and Barr was to suppress generic competition and to allow Kos to charge higher prices for Niaspan. Kos' payments to Barr under this agreement have involved large and substantial sums.

82. In 2005, Kos paid an "upfront fee" to Barr for Barr's commitment to stand by as an alternate supply source for the Kos branded product. This fee is believed to be near $5 million, which was to be supplemented with future "stand ready" quarterly fees.

83. In 2006, Kos paid Barr $45 million in royalty payments based on Kos' sales of Niaspan and Advicor, which was the "maximum annual royalty" for calendar year 2006.

84. In 2007, Kos paid Barr another $37 million, which was the maximum amount of annual royalties for that year under their co-promotion agreement for the sales of Niaspan and Advicor. Similar payments were made in subsequent years.

85. Kos gave Barr a license to sell a generic equivalent of another product -- Advicor -- and an opportunity to earn royalties on Kos' sales of Advicor prior to that generic entry, even though Advicor had not been a part of the patent dispute that was being settled. This provision of the Reverse Payment Agreement, paid Barr millions of additional dollars.

86. Kos (and its successors) continued to pay Barr (and its successor) throughout the unlawful and ongoing Agreement, and those payments involved tens of millions of dollars every year. Those payments continued into 2013.

87. In addition, the commitment by Kos (and its successors) to refrain from marketing an authorized generic version of Niaspan is worth hundreds of millions of dollars to Barr (and its successors).

88. Consistent with their unlawful Agreement, Kos and Barr took steps to conceal their unlawful conduct.

89. In the Spring of 2005, both companies repeatedly stated that the effect of the agreement was to bring a generic equivalent of Niaspan to the market in 2013, which they asserted was four years earlier than the expiration date of the last-expiring Kos Patent.

90. These statements were misleading -- and both companies knew that they were misleading -- because those statements ignored the fact that, but for the unlawful payments, Barr would have launched a generic equivalent of Niaspan At-Risk in April of 2005 and/or would have successfully negotiated for an entry date much earlier than September 2013. Thus, when Kos and Barr proclaimed that their agreement would bring generic equivalents of Niaspan to market sooner than they otherwise would have arrived, both companies knew that the real purpose and effect of their unlawful agreement was to create a very substantial delay in generic entry.

91. In the Spring of 2005, Kos and Barr both refused to disclose the amount of the payments that Kos would provide to Barr, because they had agreed to conceal the amounts of the payments that Barr was receiving. Repeatedly, when Wall Street analysts asked either company to disclose the amounts of the payments (or even the details for how the amounts would be calculated), the companies refused.

92. Kos filed copies of contracts dated April 12, 2005 with the Securities and Exchange Commission as part of its 10-Q filing dated August 9, 2005, but the publicly-filed versions of those contracts redacted the financial terms regarding the payments. Neither company reported the amounts of the payments as separate items in their financial reports. Additionally, the publicly-filed versions of the contracts contained recital clauses that falsely stated that the parties were hastening the entry of a generic equivalent of Niaspan, when in fact the parties had agreed to substantially delay generic entry.

E. Abbott Acquires Kos and Continues the Unlawful Agreement to Suppress Generic Competition

93. In November of 2006, Abbott proposed to acquire control of Kos through a tender offer transaction. Abbott offered to pay Kos shareholders $78 per share, which represented a 56% premium on the open market share price of $50 per share. At the time that Abbott made the offer, Kos' portfolio of products was still heavily dependent on Niaspan, and Kos did not have very many products in development. Thus, Niaspan (along with the above-described unlawful and ongoing Reverse Payment Agreement that was keeping Barr from launching a generic equivalent of Niaspan) was a central element of Abbott's valuation of Kos' business.

94. Abbott's tender offer was successful, and Kos was merged into Abbott in December of 2006. As Kos' successor, Abbott stepped into the shoes of Kos with respect to the ongoing unlawful Reverse Payment Agreement with Barr. Barr continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until the agreed upon launch date of September 20, 2013, and Abbott continued to make the agreed-upon payments to Barr. In this way, both parties continued with the unlawful Reverse Payment Agreement, suppressing generic competition for Niaspan.

95. Upon the completion of the merger, Abbott joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. Abbott did not withdraw from that conspiracy. Instead, Abbott participated in it.

96. The Reverse Payment Agreement was valuable to Abbott because the Agreement was postponing Barr's launch of a generic equivalent of Niaspan, and Abbott was willing to continue to pay Barr for that ongoing suppression of generic competition.

97. Over the years, U.S. retail sales of Niaspan grew as follows: 2006: $ 474 million; 2007: $ 546 million; 2008: $ 639 million; 2009: $ 717 million; 2010: $ 794 million; 2011: $1.13 billion; 2012: $ 1.03 billion.

98. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to follow the unlawful Reverse Payment Agreement that was then in place with Abbott.

99. Teva continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until September 20, 2013, and Abbott continued to make the agreed-upon payments to Teva. On September 20, 2013, Teva launched a generic product, in accordance with the Reverse Payment Agreement.

100. As a result of its acquisition of Barr, Teva also owns (either directly or indirectly) the first-filer rights held by Barr. Accordingly, no other generic company was able to launch a generic equivalent of Niaspan until the end of Teva's 180-day period as the exclusive generic seller. That is, no other generic company could introduce a generic equivalent of Niaspan until March of 2014.

101. Upon the completion of its acquisition of Barr, Teva joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. Teva did not withdraw from that conspiracy. Instead, Teva participated in it.

F. Abbott Acts to Preserve the Unlawful Agreement to Suppress Generic Competition

102. In furtherance of the unlawful and ongoing Reverse Payment Agreement with Teva, Abbott took additional steps to ensure that nothing happened to disrupt the agreement that Teva would not launch its generic until September of 2013, and to keep the generic-entry "bottleneck" in place.

103. As the first generic manufacturer to file an ANDA with a Paragraph IV Certification, Barr could not forfeit the 180-day exclusivity by failing to market the drug. Therefore, despite

agreeing with Kos to substantially delay marketing the generic, Barr still safely retained the 180-day exclusivity. By thus "parking" its 180-day exclusivity, Kos and Barr created a "bottleneck" that precluded all generic manufacturers from entering the market until 180 days after Barr entered. The intended effect of Defendants' unlawful agreement was to delay entry not only by Barr, but also by all subsequent ANDA filers.

104. In furtherance of Defendants' unlawful agreement to delay all generic entry, Kos/Abbott/AbbVie took additional action to ensure that no generic manufacturer would overcome the bottleneck. Specifically as follows:

105. On March 6, 2009, Abbott filed a patent infringement lawsuit against Lupin Limited in the United States District Court for Delaware (docketed as 09-CV-152). Abbott alleged that Lupin, a generic manufacturer, had infringed Abbott's patent by filing a Paragraph IV Certification as part of an effort to launch a generic equivalent of Niaspan. On June 13, 2012, Abbott and Lupin stipulated to a dismissal of the lawsuit. The Delaware Court never ruled on whether Lupin had infringed Abbott's patents, and there was never a final judgment on Lupin's claims that Abbott's patents were invalid or unenforceable.

106. Over the next three years, Abbott filed several more patent infringement lawsuits against generic manufacturers that had filed Paragraph IV Certifications with respect to a possible generic equivalent of Niaspan. *Abbott Laboratories v. Sun Pharmaceuticals Indus. Ltd.* (D. Del. Dkt. No. 10-CV-112); *Abbott Laboratories v. Sandoz, Inc.* (D. Del. Dkt. No. 10-CV-538); *Abbott Laboratories v. Cadila Healthcare Ltd.* (D. Del. Dkt. No. 12-CV-0065); *Abbott Laboratories v. Amnael Pharmaceuticals LLC* (D. Del Dkt. Nos. 12-CV-235 and 10-CV-1088 (consolidated)); *Abbott Laboratories v. Mylan, Inc.* (D. Del. Dkt. No. 12-CV-257); *Abbott Laboratories v. Watson Laboratories, Inc.* (D. Del. Dkt. Nos. 12-CV-324 and 12-CV-1409 (consolidated)); and *Abbott Laboratories v. Kremers Urban Pharmaceuticals, Inc.* (D. Del. 12-CV-703). Eight of those cases were dismissed by stipulation, with no final judgments entered on the infringement, the validity, or the enforceability of the patents. Only one of those cases remains pending, and it is still in discovery, with no final judgments entered on the infringement, the validity, or the enforceability of the patents.

107. In all of these lawsuits, Abbott (and its successor) was able to avoid the entry of any definitive ruling that would have disrupted the trigger date for Teva's entry into the market of its generic equivalent of Niaspan. Through delay, and through agreements (the terms of which are non-public), Abbott (and its successor) has ensured that no final judgment has been entered on non-infringement, invalidity or unenforceability of the relevant patents.

108. In light of the bottleneck created by Defendants' unlawful agreement, all of these subsequent ANDA filers agreed to delay entry into the market until 180 days after Barr/Teva entered. Absent the bottleneck created by Defendants' Reverse Payment Settlement Agreement, many or most of these later ANDA filers would have entered the market much sooner than they did.

G. Abbott Spins Off Niaspan to AbbVie, and AbbVie Continues With the Unlawful Agreement to Suppress Generic Competition

109. In 2012, Abbott announced that it was spinning off most of its prescription drug business into a new company, AbbVie. That spin-off became effective as of January 1, 2013. As Abbott's successor, AbbVie stepped into the shoes of Abbott with respect to the ongoing unlawful agreement with Teva. Teva continued to refrain from launching a generic equivalent of Niaspan, and AbbVie continued to make the agreed-upon payments to Teva.

110. Upon the transition of the Niaspan business from Abbott to AbbVie (which occurred on or about January 1, 2013), AbbVie joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. AbbVie did not withdraw from that conspiracy. Instead, AbbVie participated in it.

H. The Unlawful Agreement to Suppress Generic Competition was Ongoing, and Continued to Cause Injury

111. Until September 20th, 2013, there was no generic equivalent of Niaspan on the market in the United States. From September 20, 2013 until March of 2014, there was only one company selling a generic equivalent of Niaspan. At all relevant times, AbbVie sold all brand-name Niaspan at artificially inflated prices, and purchasers have been denied the lower prices that generic competition

would have brought to the market. This lack of generic competition has been the direct result of the ongoing unlawful Agreement.

112. The unlawful Agreement has resulted in higher prices in another way. In September of 2013, when Teva began selling its generic equivalent to Niaspan, Teva charged higher prices than it would have charged but for the Reverse Payment Agreement. Teva's higher generic prices follow from the fact that AbbVie did not launch an authorized generic during the 180 day exclusivity period, in accordance with the Reverse Payment Agreement.

113. The Defendants' unlawful conduct has been ongoing and purchasers have continued to suffer injury in the form of economic loss resulting from higher prices every day that the Defendants' unlawful agreement not to compete has remained in place, and thereafter will continue to suffer harm until the post-generic-entry market price stabilizes.

I. The Unlawful Agreement to Suppress Generic Competition Harms Competition and Causes Economic Losses to Purchasers

114. As of May 9, 2003, Barr's ANDA for a generic equivalent of the 1000 mg dosage of Niaspan was in approvable condition, and the FDA issued its Tentative Approval for that dosage. As of June 13, 2003, Barr's ANDA for a generic equivalent of the 500 mg and 750 mg dosages of Niaspan was in approvable condition, and the FDA issued its Tentative Approval for those dosages.

115. But for Defendants' anticompetitive and ongoing agreement to delay generic competition in the United States, a generic equivalent of Niaspan would have been available in the United States far earlier than September 20, 2013, the first date that a generic product became available. But for the anticompetitive, illegal and ongoing conduct described in this Complaint, a generic equivalent of Niaspan would have been available before September 20, 2013 as Barr received Final Approval from the FDA to market its generic equivalent on April 26, 2005, and Barr would have launched its generic product At-Risk. Additionally, but for the illegal conduct described in this Complaint, Kos would have launched its own authorized generic Niaspan when Barr entered, resulting in additional price competition.

116. Alternatively, but for the substantial payments Kos made to Barr, Kos and Barr would have settled their patent litigation with an agreement that would have provided for Barr to enter with generic Niaspan far earlier than September 20, 2013, on a date to be proven at trial.

117. But for the anticompetitive, illegal and ongoing conduct alleged in this Complaint, purchasers would have begun to pay less for their Niaspan prescriptions long ago. As a result, Defendants, by their conduct, have caused purchasers to pay substantial overcharges--potentially hundreds of millions of dollars--on their purchases of Niaspan.

J. The California Medicaid Program

118. The California Medicaid program is a state-administered program with federal matching funds that pays for medical care, including prescription drug benefits, for California's low-income and disabled citizens.

119. California Medicaid spending in FY 2014 alone was $492.3 billion.

120. California Medicaid currently covers approximately 11,887,524 individuals.

121. Prescription drug benefits represent approximately 16% of California Medicaid's annual budget, or approximately $78.8 billion.

122. California Medicaid reimburses medical providers, including physicians and pharmacists, for drugs prescribed for, and dispensed to, California Medicaid recipients pursuant to statutory and administrative formulas.

123. Reimbursement for pharmacy-dispensed prescription drugs under the California Medicaid program is based on information supplied by Defendants. At all times relevant to this action, Defendants were aware of the State of California's Medicaid drug reimbursement formulas and procedures for pharmacy-dispensed drugs, yet they continued their unlawful conduct in violation of California's antitrust and consumer protection laws.

124. Since April 26, 2005, Defendants have caused California's medical assistance programs to pay more for Niaspan/generic Niaspan products than they would otherwise have paid. Defendants' unlawful conduct deprived California's medical assistance programs of the benefits of competition that California's antitrust and consumer protection laws are intended to preserve.

VII. MARKET POWER AND MARKET DEFINITION

125. Direct proof exists that Kos/Abbott/AbbVie had monopoly power over the price of Niaspan in California. Such direct evidence includes transactional data showing a significant, non-transitory decline in prices of Niaspan immediately upon entry of generic versions of the drug. Such a significant, non-transitory decline in prices did not occur until generic entry into the market. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Kos/Abbott/AbbVie had monopoly power.

126. Kos/Abbott/AbbVie, as the only seller of Niaspan/extended-release niacin products in the United States, could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by its ability to profitably charge supra-competitive prices during the period in which it was without generic competition. There were no reasonably interchangeable drug products available to prescribing physicians for the indications for which Niaspan is prescribed.

127. Plaintiff alleges that the relevant market is all Niaspan products - *i.e.*, Niaspan (in all its forms and dosage strengths) and AB-rated bioequivalent Niaspan.

128. The relevant geographic market is the United States and its territories.

129. Prior to generic entry in September 2013, Kos/Abbott/AbbVie held 100% market share in the relevant market. Following market entry by generic manufacturers and much less expensive generic versions of Niaspan, Kos/Abbott/AbbVie's market share for Niaspan products declined dramatically in a short period of time.

VIII. MARKET EFFECTS

130. Defendants' unfair and unlawful scheme and anticompetitive conduct, as herein alleged, had the purpose and effect of unreasonably restraining and injuring competition by protecting Niaspan from generic competition in the relevant market.

131. Had generic competitors entered the relevant market and competed with Kos/Abbott/AbbVie, purchasers would have paid for lower-priced generics in place of the higher-priced brand name drug, resulting in far fewer dollars paid for Niaspan products between April of 2005 and generic entry in March of 2014, and continuing until the market for Niaspan stabilized.

Regulations generally permit - and sometimes even mandate - pharmacists to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. Similarly, many third-party payors of prescription drugs (e.g., managed care plans) encourage or insist on the use of generic drugs whenever possible, thus creating a ready market for generic products.

132. The initial entry of generic products generally leads to a significant erosion of a branded drug's sales within the first year as generic drugs can quickly and efficiently enter the marketplace at substantial discounts.

133. By preventing generic competitors from entering the market, Defendants injured purchasers by causing them to pay more for Niaspan than they otherwise would have paid. Defendants' unlawful conduct deprived purchasers of the benefits of competition.

IX. ANTITRUST IMPACT AND INJURY

134. During the Relevant Damage Period, Plaintiffs indirectly purchased, paid for, and/or provided reimbursements for Niaspan from Kos/Abbott/AbbVie. As a result of the Defendants' illegal conduct, purchasers were compelled to pay artificially inflated prices for Niaspan. Those prices were substantially higher than the prices that purchasers would have paid absent the illegal conduct alleged in this Complaint.

135. As a consequence, purchasers in California have sustained substantial losses in the form of overcharges. The full amount, forms, and components of such losses will be calculated after discovery and upon proof at trial.

136. Defendants' efforts to restrain competition in the market for Niaspan have substantially affected interstate and foreign commerce.

137. At all material times, Kos/Abbott/AbbVie manufactured, promoted, distributed, and sold substantial amounts of Niaspan in a continuous and uninterrupted flow of commerce within California.

138. Defendants' anticompetitive conduct had substantial effects within California. Among other things, retailers within each state were foreclosed from offering less expensive generic,

bioequivalent versions of Niaspan to purchasers. This directly impacted commerce for consumers and third-party payors, such as California purchasers.

139. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across and within California in connection with the sale of Niaspan.

140. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. See Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice (1994) at 624 (explaining that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top, and that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.")

141. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors, and that wholesalers and retailers passed on the inflated prices of Niaspan to consumers and third-party payors.

142. Defendants' anticompetitive conduct enabled Kos/Abbott/AbbVie to indirectly charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

143. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

144. The inflated prices that purchasers have paid are traceable to, and the foreseeable result of, the overcharges by Kos/Abbott/AbbVie.

145. As co-conspirators, Defendants share responsibility for each of these violations.

X. CAUSES OF ACTION

FIRST CAUSE OF ACTION

UNFAIR COMPETITION

Violation of Business and Professions Code Section 17200, et seq.

(Against all Defendants)

146. The People reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

147. Business and Professions Code Section 17200 (Section 17200) prohibits any "unlawful, unfair or fraudulent business act or practice[]." Defendants have engaged in unlawful and unfair business practices in violation of Section 17200 as set forth above.

148. Defendants' business practices as described in this Complaint constitute unlawful business acts and practices within the meaning of California Business and Professions Code section 17200. Defendants' unlawful business acts and practices as alleged herein have violated federal, state, statutory and/or common laws - and said predicate acts are therefore per se violations of section 17200. These predicate unlawful business acts and practices include, but are not limited to, the following antitrust laws: California Business and Professions Code section 16700 et seq. ("the Cartwright Act"), The Sherman Antitrust Act, 15 U.S.C. §§ 1–7, The Clayton Antitrust Act, 15 U.S.C. §§ 12-27, and the Federal Trade Commission Act, 15 U.S.C. § 45.

149. Defendants' business practices as described in this Complaint are unfair and violate Section 17200 because they offend established public policy, are substantially injurious to consumers, and because the harm they cause to consumers and purchasers in California greatly outweighs any benefits associated with those practices and the Defendants' reasons, justifications, and motives for the practices. The business acts and practices described above are also unfair in that they violate and threaten incipient violations of the aforementioned antitrust laws and violate the policy or spirit of these laws because their effects are comparable to or the same as a violation of these laws, and significantly threaten and harm competition.

150. As a direct and proximate result of the foregoing acts and practices, Defendants have received and will receive, income, profits, and other benefits, which they would not have received if

they had not engaged in the violations of Section 17200 described in this Complaint. The People therefore seek restitution from Defendants pursuant to Business & Professions Code Section 17203.

151. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained an unfair advantage over similar businesses that have not engaged in such practices.

152. Each sale of Niaspan in violation of Section 17200 constitutes a separate violation. Business & Professions Code § 17206(b). The People therefore seek civil penalties up to $2,500 per violation pursuant to Section 17206 for each violation of Section 17200. The People also seek civil penalties up to $2,500 per violation under Section 17206.1.

153. The Defendants knew or should have known that senior citizens and disabled persons would be prescribed and would purchase Niaspan, and that they would be substantially more vulnerable than other members of the public to the effects of the Defendants' conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability. As a result of the Defendants' conduct, senior citizens and disabled persons paid supracompetitive prices for Niaspan, and suffered substantial economic damage resulting from Defendants' conduct, as well as substantial loss of property set aside for retirement, personal and family care and maintenance, and assets essential to their health and welfare.

XI. PRAYER FOR RELIEF

THE PEOPLE pray that the Court:

A. Declare that Defendants have engaged in unlawful and unfair business acts and practices in violation of the Unfair Competition Law.

B. Enjoin Defendants from performing or proposing to perform any acts in violation of the Unfair Competition Law.

C. Order Defendants to pay restitution of any money acquired by Defendants' unlawful and unfair business practices, pursuant to Business and Professions Code Section 17203.

D. Order Defendants to pay civil penalties for each act of unfair and unlawful competition, pursuant to Business and Professions Code Section 17206.

E. Order Defendants to pay civil penalties for each act of unfair and unlawful competition perpetrated against senior citizens or disabled persons, pursuant to Business and Professions Code Section 17206.1, trebled according to California Civil Code Section 3345.

F. Order Defendants to pay the cost of the suit, including attorneys' fees.

G. Provide such further and additional relief as the Court deems proper.

Dated: October 4, 2016

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