# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

IN RE:

NIASPAN ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

All End-Payor Actions

MDL 2460

Master Case No. 2:13-md-2460

# END-PAYOR PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

The End-Payor Plaintiffs ("Plaintiffs"), on behalf of themselves and all others similarly situated, for their Consolidated Class Action Complaint against Defendants AbbVie Inc. ("AbbVie"), Abbott Laboratories ("Abbott"), Abbott Respiratory LLC ("Abbott Respiratory"), Barr Pharmaceuticals Inc. ("Barr"), Duramed Pharmaceuticals Inc. ("Duramed"), Duramed Pharmaceuticals Sales Corp. ("DPSC"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceuticals Industries Limited ("Teva") (collectively, "Defendants"), allege as follows based on: (a) personal knowledge of those matters relating to themselves; (b) the investigation of counsel, including the review of publicly available information, pleadings, court orders, and other filings concerning the conduct at issue in this action; and (c) information and belief.

# I. INTRODUCTION

1. Plaintiffs bring this antitrust action on behalf of a Class of End-Payors (the "Class"), *i.e.*, those at the end of the chain of distribution, that purchased, paid and/or provided reimbursement for extended-release niacin for themselves, insureds or beneficiaries for consumption and not for resale (see Class Definition below), which is sold by AbbVie (and was sold previously by Abbott and Kos Pharmaceuticals, Inc. ("Kos")) under the brand name Niaspan. For years, Niaspan was the only extended-release version of niacin approved as a once-

a-day prescription therapy for treating mixed lipid disorders. Plaintiffs seek to recover overcharge damages and other relief as a result of the harm incurred by the Class due to Defendants' anticompetitive conduct, which prevented a less expensive generic equivalent of Niaspan from entering the market for years. Defendants' anticompetitive conduct is a violation of state antitrust laws, state consumer protection laws, and state unjust enrichment laws.

- 2. The anticompetitive course of conduct described in this Consolidated Complaint was set in motion by two companies -- Kos and Barr. Niaspan was Kos' most important product, comprising nearly two-thirds of Kos' annual sales. When Barr sought regulatory approval to launch a generic equivalent of Niaspan, Kos sued Barr, alleging various patent infringement claims. By March of 2005, Barr was prepared and poised to launch its extended-release niacin generic product immediately upon receiving final approval from the FDA. In order to delay the dramatic loss of Kos' profits from Niaspan that would have occurred immediately upon Barr's launch, Kos and Barr reached an eleventh-hour, unlawful market allocation agreement pursuant to which Kos agreed to pay Barr tens of millions of dollars over the next eight years in exchange for Barr's continuing commitment not to sell an AB-rated bioequivalent generic extended-release niacin product (referred to hereafter as "generic equivalent") in competition with Niaspan (the "Reverse Payment Agreement" or "Agreement"). The essential terms of the agreement are as follows:
  - a. Kos agreed to pay Barr tens of millions of dollars in exchange for Barr's
     commitment to postpone competing with a generic equivalent of Niaspan until September
     20, 2013;

- b. Kos' payments to Barr included lump sum amounts (which Kos paid in 2005) and payments that were made as long as Barr delayed launching its generic equivalent of Niaspan (that is, until 2013);
- c. Kos and Barr disguised their payments under a spurious supply agreement and an equally spurious promotion agreement notably, Kos' payments to Barr far exceeded the value that Barr provided and Kos' real purpose for making the payments was to induce Barr to refrain from competing with Kos;
- d. In 2006, Defendant Abbott bought Kos, and Abbott continued to make payments to Barr (and its successor) in exchange for Barr continuing to refrain from competing in the Niaspan market, pursuant to the Reverse Payment Agreement;
- e. In 2008, Defendant Teva bought Barr, and Teva continued to receive payments from Abbott (and its successor) and continued to refrain from competing with its generic equivalent of Niaspan, pursuant to the Reverse Payment Agreement;
- f. In 2013, Abbott spun off its prescription drug business to AbbVie, and AbbVie has continued to make payments to Teva in exchange for Teva continuing to refrain from competing in the Niaspan market with its generic equivalent of Niaspan, under the Reverse Payment Agreement;
- g. Teva did not launch its generic equivalent of Niaspan until September 20, 2013, the date agreed upon in the Reverse Payment Agreement; and
- h. At all times, Kos/Abbott/AbbVie refrained from selling an authorized generic version of Niaspan pursuant to the Reverse Payment Agreement.
- 3. Defendants intended the Reverse Payment Agreement to create a bottleneck, preventing other generic companies from launching their own generic equivalents to Niaspan

before Barr/Teva. As the first filer of an Abbreviated New Drug Application ("ANDA") for a generic equivalent of Niaspan, Barr/Teva is entitled to market its generic product for 180 days free from competition from other generic products. The parties' Reverse Payment Agreement blocks any other generic products from coming to market until 180 days after September 20, 2013, because the FDA will not approve any subsequently-filed ANDAs until the first-filer's exclusivity period has run, which will not occur until March of 2014. Defendants have also engaged in various acts and practices, described below, to prevent any other generic company from dislodging the bottleneck.

- 4. Defendants' efforts have worked as planned, and have doubly harmed Plaintiffs and other members of the Class. In exchange for the unlawful payments from Kos/Abbott/AbbVie, Barr and Teva did, in fact, refrain from marketing a less-expensive generic equivalent of Niaspan. And when Teva finally did enter with its generic Niaspan in September 2013, pursuant to the Agreement AbbVie refrained from launching an authorized generic version of Niaspan. Thus, the Agreement resulted in very substantially delayed entry of the first generic Niaspan, and ensured that when generic entry finally did occur there was only one generic available rather than two.
- 5. But for the Reverse Payment Agreement, a generic extended-release niacin product would have been available to Plaintiffs and the Class as early as 2005. And when generic entry occurred, Kos/Abbott/AbbVie would also have launched an authorized generic version, bringing even more competition and lower prices to purchasers. Thus, absent the unlawful Reverse Payment Agreement, Plaintiffs and the members of the Class would have paid less for their prescription drug purchases. Because of Defendants' agreement to delay generic competition for Niaspan, Plaintiffs and the Class have paid hundreds of millions of dollars more

for Niaspan than they would have paid for their prescription drugs absent such conduct. At all times, the Defendants have shared in the illicit profits that have resulted from the artificially-inflated Niaspan prices.

6. Plaintiffs bring this action on their own behalf and as a class action on behalf of the Class defined below (see Paragraph 147, below). Plaintiffs seek a judgment declaring that the Reverse Payment Agreement, as further described below, is unlawful. Plaintiffs also assert claims for compensatory and/or treble damages and equitable relief for continuing violations of the State laws enumerated below.

#### II. JURISDICTION AND VENUE

- 7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, there are more than one hundred members of the Class, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.
- 8. This Court also has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.
- 9. This Court has jurisdiction over the Defendants because they are present in the United States, they do business in the United States, they have registered agents in the United States, they may be found in the United States, and/or they are otherwise subject to the service of process. Defendants have filed appearances in this matter in this Court.
- 10. Venue is appropriate within this District under 28 U.S.C. §1391(b) and (c), because Defendants transact business within this District, and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Moreover,

one of the Defendants has a facility in this District, and another Defendant is headquartered in this District. The Judicial Panel on Multidistrict Litigation has ruled that this case should proceed here for consolidated and coordinated pretrial purposes.

#### III. PARTIES

- 11. Plaintiff A.F. of L. A.G.C. Building Trades Welfare Plan (the "AFL Plan") is an employee welfare benefit plan, with its principal place of business in Mobile, Alabama. During the Class Period, as defined below, the AFL Plan purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalents (other than for resale) in Alabama, Florida, Maryland, Mississippi, and Pennsylvania. The AFL Plan paid more than it would have absent the Defendants' unlawful agreement to prevent and delay generic entry.
- 12. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address in Providence, Rhode Island. Providence is also a self-insured health and welfare benefit plan. During the Class Period, as defined below, Providence purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalent (other than for resale) in California, Connecticut, Florida, Georgia, Illinois, Iowa, Maryland, Massachusetts, Nevada, New Hampshire, Pennsylvania, Rhode Island, South Carolina, and Wyoming. Providence paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 13. Plaintiff Electrical Workers 242 and 294 Health & Welfare Fund ("EW 242/294") is an employee welfare benefit plan. EW 242/294's headquarters is located in Duluth, Minnesota. During the Class Period, as defined below, EW 242/294 purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalents

(other than for resale) in Minnesota, Ohio, Texas, and Wisconsin. EW 242/294 paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.

- 14. Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund ("IUOE Local 132") is an employee welfare benefit plan. IUOE Local 132 has its primary office in Charleston, West Virginia. During the Class Period, as defined below, IUOE Local 132 purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalents (other than for resale) in Alabama, Illinois, Florida, Kentucky, North Carolina, Ohio, Pennsylvania, Texas, Virginia and West Virginia. IUOE Local 132 paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 15. Plaintiff New England Electrical Workers Benefits Fund ("NEEWBF") is an employee welfare benefit plan. NEEWBF has its principal place of business in Wallingford, Connecticut. During the Class Period, as defined below, NEEWBF purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalents (other than for resale) in Arizona, Colorado, Connecticut, Florida, Maine, Maryland, Massachusetts, Michigan, Missouri, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, South Carolina, Tennessee, and Vermont. NEEWBF paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 16. Plaintiff Painters District Council No. 30 Health & Welfare Fund ("Painters") is an employee welfare benefit plan, with its principal place of business in Aurora, Illinois. During the Class Period, as defined below, Painters purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalents (other than for resale)

in Alabama, Florida, Georgia, Illinois, Pennsylvania, Utah and Wyoming. Painters paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.

- 17. Plaintiff United Food & Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW Local 1776"), is an employee welfare benefit plan. UFCW Local 1776's principal place of business is in Plymouth Meeting, Pennsylvania. During the Class Period, as defined below, UFCW Local 1776 purchased, paid and/or provided reimbursement for brand-name Niaspan (other than for resale) and/or its generic equivalent (other than for resale) in Arizona, Delaware, Florida, New Jersey, Pennsylvania and South Carolina. UFCW Local 1776 paid more than it would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 18. Plaintiff Miles Wallis is a resident of Tennessee. During the Class Period, as defined below, Wallis purchased brand-name Niaspan (other than for resale) and/or its generic equivalent (other than for resale) in Tennessee. Wallis paid more than he would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 19. Plaintiff Carol Prasse is a resident of Wisconsin. During the Class Period, as defined below, Prasse purchased brand-name Niaspan (other than for resale) and/or its generic equivalent (other than for resale) in Wisconsin. Prasse paid more than she would have absent Defendants' unlawful agreement to prevent and delay generic entry.
- 20. Defendant 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 in a tender offer transaction in 2006. On or about on January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie. 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.

- 21. Defendant Abbott Respiratory is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott respiratory was a wholly-owned subsidiary of Kos Pharmaceuticals, Inc., and is now a wholly-owned subsidiary of Abbott Laboratories. Abbott Respiratory is the exclusive licensee of various patents that purport to cover Niaspan and/or to cover methods of using Niaspan. At all relevant times, Defendant Abbott Respiratory engaged in the conduct challenged in this case and attributed to it and its parents, by 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. In this Consolidated Complaint, references to "Abbott" include Defendant Abbott Respiratory.
- 22. Defendant 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.
- 23. Defendant 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. 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.

- 24. Defendant Duramed is a corporation organized under the laws of the state of Delaware, with principal places 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 Womens 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.
- 25. Defendant DPSC is a corporation organized under the laws of the state of Delaware, with principal places 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. 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.
- 26. Defendant Teva 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 has employees conducting business in this District, including employees working as its Investor Relations contacts. Teva is a leading

manufacturer of generic drugs, and it is one of the largest sellers of generic drugs in the United States. 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; that launch was pursuant to the terms of the agreement that was originally reached by Kos and Barr in 2005, as discussed below.

- 27. Defendant 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 Pharmaceutical Industries, Ltd. Teva USA manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district 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.
- 28. Although not named as Defendant, Kos was one of the initiators of the unlawful agreement described in this Consolidated 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 Consolidated Complaint.

- 29. Although not named as Defendant, Kos Life Sciences, Inc. was one of the initiators of the unlawful agreement described in this Consolidated 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 whollyowned 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 Consolidated Complaint.
- 30. All of Defendants' actions described in this Consolidated 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.
- 31. 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. REGULATORY BACKGROUND - GENERIC DRUG APPROVAL PROCESS

- A. Generic Drugs Benefit Purchasers.
- 32. Generic competition enables purchasers, at all levels of the pharmaceutical supply chain, to (a) purchase generic equivalents of the brand name drug at a substantially lower price than the brand name drug, and (b) purchase the brand name drug at a reduced price. Generic competition to a branded drug product can result in billions of dollars in savings for consumers, insurers, pharmacies, and other drug purchasers.

- 33. Orally available generic solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for approval, are assigned an "AB" rating by the United States Food & Drug Administration ("FDA"). The "AB" rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter.
- 34. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription must be dispensed as written. Until a generic manufacturer enters the market, the brand name manufacturer can charge supracompetitive prices profitably without material loss of sales volume to generics.
- 35. Typically, the first AB-rated generic drug is priced significantly below its branded counterpart. Upon the entry of additional AB-rated generics, drug prices generally decline further, as more generic equivalents compete with each other.
- 36. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. In addition, many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drug's unit and dollar sales.
- 37. Once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often capturing 80% or more of the market within the first six months. For many drugs, within approximately one year after market entry, the generics have taken more than 90% of the brand's unit sales and sell for 15% of the price of the brand name product.

38. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Consequently, brand name drug manufacturers have a strong interest in delaying the start of generic competition.

## B. The FDA Oversees New Drug Approvals.

- 39. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a drug manufacturer, wishing to market a new prescription drug, must submit a New Drug Application ("NDA") to the FDA and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA. See 21 U.S.C. §355(b)(1). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. *Id.* at §§ 355(a) & (b).
- 40. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic equivalent of the brand name drug) in the FDA's "Orange Book," or book of Approved Drug Products with Therapeutic Equivalence Evaluations. 21 U.S.C. §§ 355 (b)(1) and (c)(2). New patents obtained after NDA approval must be listed in the Orange Book as related to the NDA if the new patent claims either the approved drug (for compound patents) or approved methods of use for the approved drug (for method-of-use patents). The NDA holder is required to file information on any such patent with the FDA within thirty days of the patent's issuance. 21 U.S.C. §§ 355 (b)(1) and (c)(2).
  - C. The Federal Government Encourages And Facilitates The Approval Of Generic Drugs Through The Hatch-Waxman Amendments.
- 41. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act Amendments to the FDCA, changed the approval standards

for generic drugs. (See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).) Under the Hatch-Waxman Act, once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") specifying that the generic has the same active ingredients as, and is biologically equivalent to, the already-approved brand-name drug. In this way the generic manufacturer can obtain approval while avoiding the costly and time-consuming studies needed to obtain approval for a pioneer drug. The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition.

- 42. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drug products are therapeutically equivalent and may be substituted for one another when the products: (1) contain identical amounts of the same active ingredients in the same route of administration and dosage form; (2) meet applicable standards of strength, quality, purity and identity; (3) are manufactured in compliance with current good manufacturing practices regulations; and (4) are adequately labeled. 21 U.S.C. § 355(j)(8)(B).
- 43. The Hatch-Waxman Act also sets forth special procedures for identifying, and resolving, related patent disputes. It requires the pioneer brand-name manufacturer to list in its NDA the number and the expiration date of any relevant patent. See 21 U.S.C. §355(b)(1). And it requires the generic manufacturer in its ANDA to assure the FDA that the generic will not infringe the brand-name's patents. The generic manufacturer can provide this assurance in one of several ways. See 21 U.S.C. §355(j)(2)(A)(vii). It can certify that the brand-name manufacturer

has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the drug described in the ANDA. See §355(j)(2)(A)(vii)(IV). Taking this last-mentioned route (called the "Paragraph IV" route), automatically counts as patent infringement, see 35 U.S.C. §271(e)(2)(A) (2006 ed., Supp. V), and often means provoking litigation. If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product. See 21 U.S.C. §355(j)(5)(B)(iii).

44. The Hatch-Waxman Act provides a special incentive for a generic manufacturer to be the first to file an ANDA taking the Paragraph IV route. That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug). See §355(j)(5)(B)(iv). That is, the FDA will not approve any subsequently-filed ANDA until the first-filer's 180-day exclusivity period has run. During that period of exclusivity, no other generic can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars. The vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period. The 180-day exclusivity period, however, can belong only to the first generic to file.

# D. The Impact of Authorized Generics.

- 45. 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. Competition from an authorized generic during the 180-day exclusivity period substantially reduced the first filer's revenue, and substantially reduces drug prices for consumers.
- 46. In its recent study, *Authorized Generics: Short-Term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the 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: (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.
- 47. 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 Plaintiffs and the Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.
- 48. Given the significant negative impact 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 such as Plaintiffs and the Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

- E. This Regulatory Scheme Is Susceptible To Abuse Through Anticompetitive Agreements.
- 49. Brand companies have learned how to exploit this regulatory scheme to prolong generic entry beyond lawful limits. Unscrupulous drug manufacturers can "game" the FDA statutes and regulations by paying the first filed generic to stay off the market, thus (i) withdrawing that competitive threat from the market, and (ii) "bottlenecking" approval for other would-be generic competitors. These manufacturers take advantage of two features of the Hatch-Waxman Act. First, under the Hatch-Waxman Act only the first challenger gains the special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product. And as noted, that right has proved valuable--indeed, it can be worth several hundred million dollars. Subsequent challengers cannot secure that exclusivity period, and thus stand to win significantly less than the first if they bring a successful Paragraph IV challenge. That is, if subsequent litigation results in invalidation of the patent, or a ruling that the patent is not infringed, that litigation victory will free not just the challenger to compete, but all other potential competitors too (once they obtain FDA approval). The potential reward available to a subsequent challenger being significantly less, the patentee's payment to the initial challenger (in return for not pressing the patent challenge) will not necessarily provoke subsequent challenges. Second, a generic manufacturer that files a Paragraph IV after learning that the first filer has settled will (if sued by the brand-name) have to wait out a stay period of (roughly) 30 months before the FDA may approve its application, just as the first filer did. See 21 U.S.C.

§355(j)(5)(B)(iii). These features together mean that a reverse payment to the first filer (or, as in this case, *all* of the initial filers) removes from consideration the most motivated challenger, and the one closest to introducing competition.

- 50. For Paragraph IV Certifications made before December 8, 2003, the first generic applicant could help a brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby could delay the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic created a "bottleneck" because later generic applicants could not enter the market until the first generic applicant's 180-day exclusivity had elapsed or was forfeited.
- 51. Under this type of agreement, the branded manufacturer enjoys a longer period free from generic competition, and the generic manufacturer receives a substantial payment of cash (and sometimes other valuable consideration) to do nothing until the agreed-upon date for the delayed generic entry. But purchasers suffer, because the unlawful payment denies them access to more affordable generic drugs.

## V. FACTS

- A. Niaspan Accounts For the Vast Majority of Kos' Sales Revenues.
- 52. 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.

- 53. 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.
- 54. 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)

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

- 55. 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.
- 56. 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.

- 57. 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.
- 58. 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 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.
- 59. 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.
- 60. 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.
- 61. 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.
- 62. 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.

- 63. 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 a 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.
    se lawsuits were all consolidated into one proceeding. Under the law as it existed at that time

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.

64. 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.

- 65. 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.
- 66. 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.
- 67. In these consolidated proceedings, Barr contended that Kos' patents were invalid or otherwise unenforceable, and/or not infringed.
- 68. 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.

- 69. 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.
- 70. 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.
- 71. 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.
- 72. 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.

- 73. 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 18<sup>th</sup> 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.
- 74. 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.
- 75. 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.

- 76. 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.
- 77. 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:
  - Settlement and License Agreement. Kos and Barr agreed to drop all claims and a. counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license of all of the patents arguably covering Niaspan (as listed in ¶ 41, above), 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. <u>Co-Promotion Agreement.</u> 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. <u>License and Manufacturing Agreement.</u> 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.
- 78. 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.

- 79. On April 12, 2005, the New York court dismissed all of the patent infringement cases that were pending between Barr and Kos regarding Niaspan.
- 80. On April 26, 2005, the FDA gave Kos final approval for its generic equivalent of Niaspan, in all doses.
- 81. 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.
- 82. 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).
- 83. 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. And these payments caused Barr to agree to stay out of the market longer than it otherwise would have done. Kos agreed to pay Bar to delay entry into the market.
- 84. 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. Specifically:
  - a. 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. Plaintiffs would have paid lower prices -- on both brand name Niaspan and on the generic equivalent of Niaspan -- than they otherwise paid.
  - b. 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.

- c. 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 after 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.
- 85. 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.
- 86. Kos' payments to Barr under this agreement have involved large and substantial sums.
  - a. 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 in the ballpark of \$5 million, which was to be supplemented with future "stand ready" quarterly fees.
  - b. 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.
  - c. In 2007, Kos paid Barr another \$37 million, which was the maximum annual royalties for that year under their co-promotion agreement for the sales of Niaspan and Advicor. Similar payments were made in subsequent years.
  - d. 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.

- e. 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.
- f. 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).
- 87. Consistent with their unlawful Agreement, Kos and Barr took steps to conceal their unlawful conduct.
  - a. 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. 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.

- b. 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.
- c. 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 very substantially delay generic entry very substantially.
- E. Abbott Acquires Kos And Continues the Unlawful Agreement to Suppress Generic Competition.
- 88. 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.

- 89. 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.
- 90. 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.
- 91. 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.
  - 92. 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

- F. Teva Acquires Barr and Continues the Unlawful Agreement to Suppress Generic Competition.
- 93. 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. 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.

- 94. 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 is able to launch a generic equivalent of Niaspan until Teva has had a 180-day period as the exclusive generic seller. That is, no other generic company can introduce a generic equivalent of Niaspan until March of 2014.
- 95. 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.
  - G. Abbott Acts to Preserve the Unlawful Agreement to Suppress Generic Competition.
- 96. 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.
- 97. 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 retaining 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.

- 98. 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:
  - a. 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.
  - b. 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.

- 99. 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.
- 100. 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.

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

101. 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.

- 102. Upon the transition of the Niaspan business from Abbott to AbbVie (which occurred on or about on 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.
  - I. The Unlawful Agreement to Suppress Generic Competition is Ongoing, and It Continues to Cause Injury.
- 103. Until recently, there was no generic equivalent of Niaspan on the market in the United States. Even today, there is only one company selling a generic equivalent of Niaspan. At all relevant times, AbbVie has sold, and continues to sell, brand-name Niaspan at artificially inflated prices, and Plaintiffs and the Class 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.
- 104. 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 has not launched an authorized generic, in accordance with the Reverse Payment Agreement.
- 105. During the four-year period before the filing of the earliest complaint in this litigation, the Defendants' unlawful conduct has been ongoing and the Plaintiffs and the Class have continued to suffer injury every day that the Defendants' unlawful agreement not to compete has remained in place. During the applicable limitations period, the Defendants have

operated under an ongoing agreement to suppress generic competition, and Plaintiffs and the Class have been injured by the Defendants' conduct.

- J. The Unlawful Agreement to Suppress Generic Competition Harms Competition, Injures the Plaintiffs, and Causes Damages.
- 106. As of May 9, 2003, Barr's ANDA for a generic equivalent of the 1000 mg dosage of Niaspan ANDA 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.
- 107. 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 Consolidated 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 Consolidated Complaint, Kos would have launched its own authorized generic Niaspan when Barr entered, resulting in additional price competition.
- 108. Alternatively, but for the substantial payments Kos made to Barr, Kos and Barr would have settled their patent litigation with an agreement that provided for Barr to enter with generic Niaspan far earlier than September 20, 2013, on a date to be proven at trial.
- 109. But for the anticompetitive, illegal and ongoing conduct alleged in this
  Consolidated Complaint, Plaintiffs and members of the Class would have begun to pay less for

their Niaspan requirements long ago. As a result, Defendants, by their conduct, have injured Plaintiffs and the Class by causing them to pay substantial overcharges -- potentially hundreds of millions of dollars -- on their purchases.

# VI. MARKET CHARACTERISITICS

- 110. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that branded drug manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and payment obligation, the price of the product plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to lower the prices of their products.
- 111. The pharmaceutical marketplace, however, is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Niaspan, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product.
- 112. Brand manufacturers, including Kos/Abbott/AbbVie exploit this price disconnect by employing large sales forces who visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are

insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

- what economists call the price elasticity of demand -- the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is brand manufacturers gaining and maintaining market power with respect to many branded prescription pharmaceuticals, including Niaspan.
- 114. The existence of other products designed to treat mixed lipid disorders has not significantly constrained Kos/Abbott/AbbVie's pricing of Niaspan. At all relevant times, Kos/Abbott/AbbVie's price for Niaspan has been at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs.

  Kos/Abbott/AbbVie has never lowered the price of Niaspan in response to the pricing of other branded treatments for mixed lipid disorders (or the generic versions of such medications).
- would be a uniquely significant market event. Kos/Abbott/AbbVie predicted that unlike the entry of other branded treatments for mixed lipid disorders (or the generic versions of such medications), entry of generic Niaspan would take substantial unit sales from Kos/Abbott/AbbVie. For example, Kos/Abbott/AbbVie predicted entry of generic Niaspan would immediately cause branded Niaspan to lose well more than half of its unit sales. Likewise, Barr estimated its generic equivalent of Niaspan would take essentially all of its sales from

branded Niaspan and few, if any, sales from other branded drugs that treat mixed lipid disorders (or generic versions of such medications). Kos predicted the same with respect to its potential authorized generic version of Niaspan.

- 116. Kos/Abbott/AbbVie and Barr predicted that the competitive impact of generic Niaspan would be substantial. Among other things, all of the Defendants predicted the availability of generic Niaspan would deliver hundreds of millions of dollars of savings to consumers.
- 117. Kos, Abbott and AbbVie had the power to maintain the price of Niaspan products (meaning Niaspan in all its dosage strengths) at supracompetitive levels without losing substantial sales to other products.
- 118. A small but significant, non-transitory price increase for Niaspan would not have caused a significant loss of sales so as to make the higher prices unprofitable.
- 119. At competitive price levels, Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than an AB-rated generic equivalent of Niaspan, which only entered the market on September 20, 2013.
- 120. Because of, among other reasons, its unique profile as a once-a-day Niacin therapy for treating mixed lipid disorders, Niaspan is differentiated from all products other than AB-rated generic equivalents of Niaspan.
- 121. Kos, Abbott, and AbbVie needed to control only Niaspan and any AB-rated generic equivalents for Niaspan, and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices.
- 122. Kos, Abbott and AbbVie also sold branded Niaspan at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

- 123. Defendants have had, and exercised, the power to exclude generic competition to branded Niaspan.
- 124. Defendants, at all relevant times, enjoyed high barriers to entry with respect to the market for Niaspan products.
- 125. To the extent that Plaintiffs are legally required to define a relevant product market, Plaintiffs allege that the relevant market is all Niaspan products -- *i.e.*, Niaspan (in all its dosage strengths) and any AB-rated bioequivalent products. During the period relevant to this case, Defendants have profitably maintained the price of Niaspan products well above competitive levels.
  - 126. The relevant geographic market is the United States and its territories.
- 127. During most of the Class Period, Kos, Abbott, and AbbVie had a 100% market share in the relevant market, and continued to have that market share until September 20, 2013. For the period from September 20, 2013 until March of 2014, the Defendants are sharing a 100% market share in the relevant market.

# VII. MARKET EFFECTS

- 128. Kos began to ship Niaspan to Plaintiffs and other members of the Class on or shortly after July 28, 1997, after receiving the FDA's formal, written final approval of its NDA. From then until September 20, 2013, no generic equivalent of Niaspan was available for sale in the United States.
- 129. Defendants' Reverse Payment Agreement had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Niaspan from generic competition. But for the unlawful Reverse Payment Agreement, Barr would have entered the market with a generic equivalent of Niaspan much earlier than September 2013,, and one or

more generic equivalents of Niaspan would have been on the market at all times after Barr entered. The Defendants' Reverse Payment Agreement allowed Kos (and later Abbott and AbbVie) to exclude competition in the market for Niaspan products, leading to higher prices paid by Plaintiffs and all other members of the Class.

- 130. But for the Defendants' anticompetitive agreement, Kos would have launched an authorized generic to compete with Barr as soon as Barr entered. Other generic manufacturers would have entered the market at some point after Barr's 180-day exclusivity period expired.
- 131. But for the Defendants' illegal conduct, generic competition would have forced down the price of branded Niaspan, and price competition among the generic suppliers would have been intense.
- 132. But for the Defendants' illegal conduct, Plaintiffs and members of the Class would have paid less for Niaspan and/or its AB-rated bioequivalent products. The Defendants' conduct directly injured Plaintiffs and the Class by forcing them to pay hundreds of millions of dollars in overcharges.
- 133. As a result of the delay in generic competition brought about by the Defendants' Reverse Payment Agreement, Plaintiffs and the Class paid more for Niaspan products than they would have paid absent Defendants' illegal conduct.
- 134. Barr, Teva and the other ANDA applicants seeking to market generic equivalents to Niaspan had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand, marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

- 135. Upon generic entry, generic equivalents of brand-name drugs are priced significantly below the branded drug to which they are AB-rated. As a result, upon generic entry, virtually all branded drug purchases are rapidly switched to generic equivalents of the drug. As more generic manufacturers enter the market, prices for a generic equivalent of a drug fall even further because of increasing price competition.
- 136. This price competition enables all end-payors of the drugs to: (a) purchase generic equivalents of the drug at a substantially lower price than the brand; (b) purchase generic equivalents of the drug at a lower price; and/or (c) purchase the brand drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.
- 137. If generic competitors had not been unlawfully prevented from entering the market, end-payors, such as Plaintiffs and members of the Class, would have paid less for Niaspan products by (a) substituting purchases of less-expensive AB-rated generic equivalents of Niaspan for their purchases of more-expensive brand-name Niaspan, and (b) purchasing brand-name Niaspan at a reduced price.
- 138. Moreover, due to the Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic equivalents of Niaspan.
- 139. Thus, the Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

# VIII. ANTITRUST IMPACT

140. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Niaspan indirectly from Kos, Abbott and AbbVie. As a result of

Defendants' illegal conduct, members of the Class were compelled to pay artificially inflated prices for their Niaspan requirements at the point of sale (*e.g.*, the pharmacy counter or mail order pharmacy). Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein. Class members were deprived of the opportunity to purchase lower-priced generic equivalents of Niaspan, and suffered antitrust impact at the point of sale.

- 141. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.
- 142. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Niaspan to the Plaintiffs and members of the Class.
- 143. The Defendants' anticompetitive actions enabled Kos, Abbott and 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.
- 144. The prices were inflated as a direct and foreseeable result of the Defendants' anticompetitive conduct.
- 145. The inflated prices that the Class has paid are traceable to, and the foreseeable result of, the overcharges by Kos, Abbott and AbbVie.

### IX. CLASS ACTION ALLEGATIONS

- 146. Plaintiffs, on behalf of themselves and all Class members, seek damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Niaspan.
- 147. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), and (b)(3), as representatives of a Class defined as follows:

All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Niaspan (or a generic equivalent of Niaspan), in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class"), other than for resale, from any of the Defendants or their predecessors, during the period March 30, 2005 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

- 148. The following persons or entities are excluded from the proposed Class:
- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- All federal or state government entities other than cities, towns or municipalities
   with self-funded prescription drug plans;
- c. All persons or entities who purchased Niaspan for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);
- e. Flat co-payers (*i.e.*, consumers who paid the same co-payment amount for brand and generic drugs);

- f. The judges in this case and any members of their immediate families; and
- g. All Counsel of Record.
- 149. Except for transactions, if any, that are subject to capitation agreements, Pharmacy Benefit Managers ("PBMs"), which transmit payments to pharmacies as part of the administrative services they perform for third party payors, do not fit the definition of the Class and are not Class members.
- 150. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are hundreds of thousands of Class members.
- 151. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Niaspan and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Niaspan as a result of the Defendants' wrongful conduct.
- 152. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Class.
- 153. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation—especially involving pharmaceutical products.
- 154. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

- 155. Questions of law and fact common to the Class include:
- a. whether Kos, Abbott or AbbVie entered into a contract, combination, and/or conspiracy with Barr or Teva to restrain trade;
- b. whether Kos (and its successors) paid cash and/or other valuable consideration to Barr (and its successors) as compensation for a promise to delay the launch of a generic product that would have competed with Niaspan;
- c. whether Defendants unlawfully excluded competitors and/or potential competitors from the market for Niaspan;
- d. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;
- e. whether the activities of Defendants as alleged herein have substantially affected interstate and instrastate commerce;
- f. whether the Defendants have a pro-competitive justification for their conduct, and if so, whether that justification outweighs the anticompetitive impact of their conduct;
- g. whether, and to what extent, Defendants' conduct caused antitrust injury(e.g., overcharges) to Plaintiffs and the members of the Class; and
- h. the quantum of aggregate overcharge damages to be awarded to the Class.
- 156. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed 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 the management of this class action.

- 157. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.
- 158. If required, Plaintiffs will propose one or more subclass(es), as the record becomes more developed.

### X. INTERSTATE AND INTRASTATE COMMERCE

- 159. Defendants' anticompetitive conduct has affected interstate, intrastate and foreign commerce.
- 160. At all relevant times, Kos, Abbott and/or AbbVie have manufactured, promoted, distributed, and sold substantial amounts of Niaspan in a continuous and uninterrupted flow of commerce throughout the United States and across state and national lines. In furtherance thereof, at all relevant times, Defendants have transmitted funds, contract, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce throughout the United States and across state and national lines.
- 161. Defendants' anticompetitive conduct had and continues to have substantial intrastate effects. Among other things, it prevented, until September 20, 2013, any and all generic competition from entering the market for extended release niacin, thus preventing retailers within each state from offering generic equivalents of Niaspan to End-Payors within their respective states.

# XI. FRAUDULENT CONCEALMENT TOLLING THE STATUTE OF LIMITATIONS

- 162. Plaintiffs and members of the Class had no knowledge of Defendants' unlawful self-concealing agreement and could not have discovered the conspiracy through the exercise of reasonable diligence during the applicable limitations periods.
- 163. This is so both because the nature of Defendants' conspiracy was self-concealing and because Defendants employed deceptive practices and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and conduct. Notwithstanding the self-concealing nature of their conspiracy, Defendants and their coconspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from Plaintiffs by, among other things:
  - a. Concealing the amounts that Kos was to pay to Barr under the Agreement;
  - b. Concealing the fact that those amounts far exceeded any lawful economic benefit that Kos received from Barr under the Agreement;
  - c. Issuing a Joint Press Release on April 13, 2005 that claimed that those payments were compensation for Barr promoting Niaspan to obstetricians and gynecologists, and as compensation for Barr agreeing to stand by as a backup supplier, when in fact Kos was paying Barr not to launch a generic equivalent of Niaspan;
  - d. In that same Joint Press Release, proclaiming that the Agreement would permit Barr to launch a generic equivalent to Niaspan in 2013, which was supposedly "approximately four years earlier than the last-to-expire Kos patent," without stating that the Agreement substantially delayed generic entry, by both Barr and Kos, compared to when it would have occurred absent the unlawful payments;

- e. Repeating those false and misleading statements about the Agreement (along with other similarly misleading statements about the Agreement) in publicly-filed documents (including Kos' 10-K filing dated March 16, 2005 at pp. 13-14, 18-19; Kos' 10-Q filing dated May 10, 2005 at p. 15; Kos' 10-Q filing dated August 9, 2005, at p. 24; Kos' 10-Q filing dated November 9, 2005, at p. 25; Kos 10-K filing dated March 10, 2006, at pp. 4, 26; Kos' 10-Q filing dated May 10, 2006 at pp. 23, 28-29; Kos' 10-Q filing dated September 14, 2006 at pp. 35, 41; Kos' 10-Q filing dated November 9, 2006 at pp. 29, 33; Barr's 10-Q filing dated November 2, 2005, at pp. 17-18; Barr's 10-Q filing dated May 6, 2005, at pp. 18-19; and Barr's 10-K filing dated September 13, 2005);
- f. Repeating those same false and misleading statements in the Agreement (including ¶ 4 of the Co-Promotion Agreement; Article 7 of the License and Manufacturing Agreement; and the "Whereas" clauses of the Settlement and License Agreement);
- g. During conference calls with investment bank analysts, refusing to answer direct questions from analysts in the financial community who asked about the financial terms of the payments that Kos was making to Barr (including an April 13, 2005 Conference Call, in which Barr's Chief Executive Officer Bruce Downey refused to provide details when asked about the financial terms of the Agreement, and including an August 4, 2005 Conference Call, in which Kos' Interim Chief Financial Officer Juan Rodriguez refused to provide details of those financial terms); and
- h. Filing misleadingly redacted versions of the Agreement with the United States Securities and Exchange Commission (Submitted as Exhibits 10.2, 10.3 and 10.4 to Kos' 10-Q filing dated August 9, 2005), so as to conceal the financial terms of the Agreement.

- 164. Because the conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiffs and members of the Class had no knowledge of the conspiracy or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.
- 165. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting the Plaintiffs' and the Class's claims have been tolled.

### XII. CONTINUING VIOLATION

166. This Consolidated Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations.. Thus, Plaintiffs and the members of the Class can recover for damages that they suffered during any applicable limitations period.

### XIII. CLAIMS FOR RELIEF

# **FIRST CLAIM FOR RELIEF**

For Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

- 167. Plaintiffs incorporate by reference the preceding allegations and paragraphs.
- 168. In 2005, Kos and Barr entered into an Agreement to suppress generic competition for Niaspan, and the Agreement has continued as an ongoing agreement since then. Abbott, Teva and AbbVie each joined and continued the unlawful Agreement to suppress generic competition. The Agreement has involved the conduct set forth above. The Agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

- a. Allocate all sales of Niaspan in the United States to Kos, Abbott and AbbVie until September 20, 2013;
- b. Prevent each of the participating companies from selling a generic equivalent or version of Niaspan in the United States until September 20, 2013;
- c. Prevent other generic manufacturers from selling generic equivalents of Niaspan in the United States until 2014;
- d. Fix the price that Plaintiffs and members of the Class would pay for Niaspan; and
- e. Fix the price that Plaintiffs and members of the Class would pay for a generic equivalent to Niaspan when that product launched.
- 169. The Agreement has harmed Plaintiffs and the Class as set forth above.
- 170. The Agreement has covered a sufficiently substantial percentage of the relevant market to harm competition.
- 171. The Agreement between Defendants is a horizontal market allocation and price fixing agreement between actual and potential competitors and is an unreasonable restraint of trade, in violation of state antitrust law, under a "rule of reason" analysis.
- 172. There is and was no legitimate, non-pretextual, procompetitive business justification for the Agreement that outweighs its harmful effect. Even if there were such a justification, the Agreement is and was broader than necessary to achieve any conceivable procompetitive purpose.
- 173. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a conspiracy or combination in restraint of trade, in violation of the following state antitrust laws:
  - a. Arizona Rev. Stat. §§ 44-1402, et seq., with respect to purchases (or

payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Arizona by members of the Class;

- b. Cal. Bus. & Prof Code §§ 16700, *et seq.*, and California common law with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in California by members of the Class;
- c. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in the District of Columbia by members of the Class;
- d. Iowa Code §§ 553 *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Iowa by members of the Class;
- e. Kansas Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Kansas by members of the Class;
- f. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Maine by members of the Class;
- g. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Michigan by members of the Class;
- h. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its

generic equivalent) in Minnesota by members of the Class;

- i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Mississippi by members of the Class;
- j. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Nebraska by members of the Class;
- k. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Nevada by members of the Class;
- 1. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in New Mexico by members of the Class;
- m. New York General Business Law § 340, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in New York by members of the Class;
- n. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in North Carolina by members of the Class;
- o. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in North Dakota by members of the Class;
- p. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases (or payments

- of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Oregon by members of the Class;
- q. R.I Gen Laws §§ 6-36-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Rhode Island by members of the Class;
- r. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Tennessee by members of the Class;
- s. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Utah by members of the Class who are either citizens of Utah or residents of Utah;
- t. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Vermont by members of the Class;
- u. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in West Virginia by members of the Class; and
- v. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Wisconsin by members of the Class.
- 174. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist

- of: (1) being denied the opportunity to purchase lower-priced generic equivalents to Niaspan, and (2) paying higher prices for Niaspan products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.
- 175. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable for all damages resulting from their own unlawful conduct.
- 176. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable for all damages resulting from its own unlawful conduct.
- 177. Under the applicable state statutes, all required notices have been sent to the relevant state agencies with respect to these claims.
- 178. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations.
- 179. The Defendants are jointly and severally liable for all damages suffered by the Plaintiffs and the members of the Class.

# **SECOND CLAIM FOR RELIEF**

# For Unfair And Deceptive Trade Practices Under State Law (Against All Defendants)

- 180. Plaintiffs incorporate by reference the preceding allegations and paragraphs.
- 181. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic equivalent of Niaspan and forced to pay higher prices for their Niaspan requirements.
- 182. For years, there was a gross disparity between the price that Plaintiffs and the Class members paid for the brand product and the value received, given that much cheaper substitute generic products should have been available.
- 183. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer fraud laws:
  - a. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in California by members of the Class;
  - b. 6 Del. C. § 2533, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Delaware by members of the Class;
  - c. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its

generic equivalent) in the District of Columbia by members of the Class;

- d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Niaspan (and its generic equivalent) in Florida by members of the Class;
- e. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Massachusetts by members of the Class;
- f. Minn. Stat. §§ 325F.68, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Minnesota by members of the Class;
- g. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Missouri by members of the Class;
- h. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Nebraska by members of the Class;
- i. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in New Hampshire by members of the Class;
- j. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in New Mexico by members of the Class;
- k. N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases (or

payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in New York by members of the Class;

- 1. N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in North Carolina by members of the Class;
- m. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Pennsylvania by members of the Class;
- n. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Rhode Island by members of the Class
- o. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in South Dakota by members of the Class;
- p. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) of Niaspan (and its generic equivalent) in Tennessee by members of the Class; and
- q. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases (or payments of, or reimbursements of, some or all of the purchase price) of Niaspan (and its generic equivalent) in Virginia by members of the Class.
- 184. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim.

Their injury consists of paying higher prices for Niaspan than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

- 185. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable to all damages resulting from their own unlawful conduct.
- 186. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable to all damages resulting from its own unlawful conduct.
- 187. Under the applicable state statutes, all required notices have been sent to the relevant state agencies with respect to these claims.
- 188. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations.
- 189. To the extent permitted by applicable law, the Defendants are jointly and severally liable for all damages suffered by the Plaintiffs and the members of the Class.

### THIRD CLAIM FOR RELIEF

**Unjust Enrichment** (**Against All Defendants**)

- 190. Plaintiffs incorporate by reference the preceding allegations and paragraphs.
- 191. To the extent required, this Third Claim is pled in the alternative from all other Claims in this Consolidated Complaint. Plaintiffs bring this claim under the laws of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the District of Columbia and other United States territories.
- 192. Defendants have benefited from the overcharges on their sales of Niaspan resulting from the unlawful and inequitable acts alleged in this Consolidated Complaint.
- 193. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Niaspan by Plaintiffs and members of the Class.
- 194. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiffs and the Class.
- 195. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

- 196. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Niaspan, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.
- 197. The economic benefit derived by Defendants through charging supracompetitive and artificially inflated prices for Niaspan is a direct and proximate result of Defendants' unlawful practices.
- 198. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive prices during the Class Period, inuring to the benefit of Defendants.
- 199. It would be inequitable under unjust enrichment principles for the Defendants to be permitted to retain any of the overcharges for Niaspan derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Consolidated Complaint.
- 200. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs and the Class.
- 201. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.
- 202. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.
  - 203. Plaintiffs and the Class have no adequate remedy at law.
- 204. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade,

Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable to all damages resulting from their own unlawful conduct.

205. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable to all damages resulting from its own unlawful conduct.

### XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, demand judgment for the following relief:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R.
  Civ. P. 23(a), and (b)(3), direct that reasonable notice of this action, as provided by Fed.
  R. Civ. P. 23(c)(2), be given to the Class, and declare that the Plaintiffs are proper representatives of the Class;
- B. Declare that the conduct alleged herein is in violation of the statutes as set forth above, and of the common law of unjust enrichment as set forth above;
- C. Enter joint and several judgments against Defendants in favor of Plaintiffs and the Class;
- D. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

- E. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- F. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and
- G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

### XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

January 15, 2014

/s/ Kenneth A. Wexler

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