UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PROFESSIONAL DRUG COMPANY, INC., on behalf of itself and all others similarly situated, Plaintiff, v. ABBOTT LABORATORIES, ABBVIE, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD, BARR PHARMACEUTICALS, INC., DURAMED PHARMACEUTICALS, INC., and DURAMED PHARMACEUTICALS SALES CORP., Defendants.	Civil Action No. _____ **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Professional Drug Company, Inc., on behalf of itself and all others similarly situated, for its complaint against defendants Abbott Laboratories, AbbVie Inc. ("AbbVie"), (together with Abbott Laboratories, "Abbott"), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited (collectively "Teva"), Barr Pharmaceuticals Inc. ("Barr"), Duramed Pharmaceuticals Inc. ("Duramed"), and Duramed Pharmaceuticals Sales Corp. ("DPSC"), alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of defendants' conspiracy to allocate, and unreasonably restrain trade in, the market for brand and generic

versions of the prescription drug Niaspan, an extended-release version of niacin, which is sold by AbbVie (and was sold previously by Abbott and Kos Pharmaceuticals, Inc. ("Kos")). Niaspan is the only extended-release version of niacin approved as a once-a-day prescription therapy for treating mixed lipid disorders. Professional Drug seeks to recover overcharge damages incurred by the class due to defendants' anticompetitive conduct, which delayed entry of less expensive generic equivalents of Niaspan in violation of the federal antitrust laws.

2. The alleged anticompetitive-conduct by Kos is not the first time that Kos engaged in unlawful behavior to increase its revenues and profits from Niaspan. Kos and Abbott agreed in 2010 to pay $41 million to the Government to resolve allegations of Kos paying illegal kickbacks and off-label marketing of Niaspan. "Kos entered into a deferred prosecution agreement and agreed to the filing of criminal information in U.S. District Court for the Middle District of Louisiana charging the company with one count of conspiracy to violate the Anti-Kickback Statute. According to the criminal information, Kos conspired to violate the statute by agreeing to pay physicians kickbacks in exchange for their writing prescriptions for Kos drugs." In connection with that settlement, Tony West, Assistant Attorney General for the Civil Division of the Department of Justice, explained that "[p]harmaceutical companies that pay kickbacks to medical professionals take from the taxpayers and undermine the integrity of choices that doctors make for their patients[.]"

3. Kos' unlawful conduct extended beyond its admittedly unlawful marketing to its anticompetitive efforts, alleged here, to delay entry of generic versions of Niaspan. Generic versions of brand name drugs contain the same active ingredient, and are determined by the Food and Drug Administration ("FDA") to be just as safe and effective, as their brand name counterparts. The only difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand counterparts when there is a single

generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers.

4. Those same savings are viewed as a grave threat by brand name drug companies such as Abbott and Kos. FDA-approved, AB-rated generic versions of brand drugs typically take 80% or more of the unit sales of the brand product soon after generic entry. The Federal Trade Commission estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product.

5. The anticompetitive course of conduct described in this complaint was set in motion by two companies: Kos and Barr. Niaspan was Kos's key product, accounting for the vast majority of Kos's revenues and profits. When Barr sought regulatory approval to launch a generic equivalent of Niaspan, Kos sued Barr, alleging various patent infringement claims.

6. In order to delay the drastic loss of its monopoly profits from Niaspan, Kos (later acquired by Abbott) engineered a scheme whereby it would buy its way out of competition with Barr (later acquired by Teva) and mitigate the likelihood that its Niaspan patents would be invalidated. Specifically, Kos agreed to pay Barr – both in cash and by agreeing not to launch an authorized generic version of Niaspan when Barr eventually launched its generic – to not enter the market until September 20, 2013 and to drop its challenge to the Niaspan patents. Kos and Barr attempted to disguise these payments (frequently called "exclusion payments" or "reverse payments") as payments for Barr promoting Niaspan and for Barr serving as a back-up supplier to Kos. Defendants intentionally concealed the true purpose and nature of their exclusion payments in a futile attempt to escape liability under the antitrust laws.

7. In March of 2005, Barr was prepared and poised to launch its extended-release niacin product immediately upon receiving final approval from the FDA. In order to delay the

drastic 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 millions of dollars to Barr over the next eight years in exchange for Barr's continuing commitment not to sell an extended-release niacin product in competition with Niaspan (the "Exclusion Payment Agreement" or "Agreement"). Specifically:

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 includes:

   i. lump sum amounts (which Kos paid in 2005);

   ii. quarterly payments that have been made so long as Barr delayed launching its generic equivalent of Niaspan (that is, Kos, Abbott, and AbbVie have been making those payments on a quarterly basis ever since 2005); and

   iii. the incredibly valuable agreement by Kos not to launch an authorized generic version of Niaspan during Barr's 180-day exclusivity period – the period during which Barr will realize the majority of its profits on generic Niaspan unless Kos or Abbott launches an authorized generic; with a drug of Niaspan's size this agreement not to launch an authorized generic can be worth hundreds of millions of dollars.

c. Kos and Barr cloaked their payments behind a spurious supply agreement and an equally spurious promotion agreement, but 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, Abbott bought Kos, and Abbott continued to make payments to Barr

(and its successor) in exchange for Barr continuing to delay competing with Niaspan, under the Exclusion Payment Agreement;

e. In 2008, Teva bought Barr, and Teva has continued to receive payments from Abbott (and its successor) and has continued to delay competing with its generic equivalent of Niaspan, under the Exclusion Payment Agreement; and

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 delay competing with its generic equivalent of Niaspan, under the Exclusion Payment Agreement.

8. Moreover, the defendants knew and intended that the Exclusion Payment Agreement would also prevent other generic companies from launching their own generic Niaspan before Barr/Teva did, thereby creating a bottleneck. 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 Niaspan for 180 days free from competition from other generic products. The parties' Exclusion Payment Agreement can block any other generic Niaspan 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 180 days after Teva launches. Abbott has also engaged in various acts and practices, described below, to prevent any other generic company from dislodging the FDA approval bottleneck created by the Exclusion Payment Agreement.

9. Defendants' scheme has worked as planned. Barr and Teva have, in fact, delayed marketing a less-expensive generic equivalent of Niaspan. But for the Exclusion Payment Agreement, a generic extended-release niacin product would have been available to Professional Drug and the class substantially earlier than 2013. Thus, absent the unlawful Exclusion Payment

Agreement, Professional Drug and the members of the class would have paid less for their prescription drug purchases. Because of the defendants' scheme to delay generic competition for Niaspan, Professional Drug 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 prices for Niaspan.

10. Defendants' unlawful Exclusion Payment Agreement was designed to and in fact did: (a) preclude the entry of less expensive generic equivalents of Niaspan in the United States; and (b) fix, raise, maintain or stabilize the price of extended-release niacin products, above the levels that would have otherwise existed if there had been competition. Because of the defendants' scheme to delay generic competition for Niaspan, Professional Drug and the class have paid hundreds of millions of dollars more for Niaspan than they would have paid absent such conduct.

11. Although the Exclusion Payment Agreement purported to settle patent infringement suits that Kos filed against Barr with respect to patents that purportedly cover Niaspan, Kos used the strength of its wallet as opposed to the strength of its patents to obtain Barr's agreement not to launch its generic version of Niaspan. In light of the substantial possibility that Kos's Niaspan patents would be invalidated and/or that the generics' products would be adjudged non-infringing – in which case Kos would have been unable to keep generic versions of Niaspan from swiftly taking the vast majority of sales from Niaspan – Kos agreed to share its monopoly rents with Barr as the *quid pro quo* for Barr's agreement not to compete with Kos in the delayed-release niacin market until September 13, 2013.

12. Like Kos, Barr knew that it would be more profitable to be paid not to compete than to enter the market. Had Barr and other generic manufacturers launched generic versions of

Niaspan, as they were preparing and poised to do, the competition among them would have driven down the price of generic Niaspan. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with little to distinguish one generic from another except price. While such competitive generic sales are still profitable, it can be substantially more profitable to be paid by the brand company not to compete. Barr was well aware of these market dynamics, and knew that, rather than entering the market and competing, it could make more profit by agreeing to delay entry in exchange for a portion of Kos's monopoly profits from Niaspan, paid in the form of an Exclusion Payment. And that is precisely what happened.

13. Both Kos and Barr were highly incentivized in 2005 to settle their patent infringement litigation. Niaspan constituted the vast majority of Kos's company-wide sales revenue from 2001 through 2005, and losing that revenue stream – as Kos would have if the patents were held invalid, unenforceable or not-infringed – would have materially impacted its profits. This concern was heightened by Kos's desire to sell itself, a goal ultimately fulfilled with Kos's 2006 acquisition by Abbott. Had Kos lost its major revenue stream from Niaspan, Abbott would have paid vastly less for Kos. Kos, therefore, was desperate to settle the patent litigation with Barr. Even Barr acknowledged that the patent infringement litigation "was literally 'bet-the-company' for Kos because Niaspan provided over 80 percent of the company's profit's to support its $1.8 billion market capitalization."

14. Barr, too, desired to settle the patent litigation, as evidenced by Barr's decision to enter into the anticompetitive settlement with Kos. Barr was so convinced that Kos's patents did not protect against Barr's version of generic Niaspan that Barr was willing to and was taking substantial steps in preparation for an imminent at-risk launch. Though Barr was willing to launch at-risk, it had never before done so. And an at-risk launch, as the name implies, carries

the risk of a substantial damages judgment if the challenged patent is ultimately upheld and the found to be infringed by the generic manufacturer's product. The risks pushed Barr to want to settle the infringement litigation, notwithstanding Barr's readiness and willingness to launch at risk. Kos knew that Barr (absent a settlement of the patent litigation) was going to launch at-risk, as evidenced by Kos's decision to produce an authorized generic version of Niaspan to launch and immediately counter Barr when launched at-risk. Of course, once the erstwhile competitors decided to collude instead of compete, Kos, as part of the Exclusion Payment Agreement, agreed to not launch an authorized generic version of Niaspan.

15. Given both Kos's and Barr's desire to settle the Niaspan patent infringement litigation, and absent their actual anticompetitive agreement, Kos and Barr would have entered into a procompetitive settlement agreement that would have allowed for sustained entry of less-expensive generic Niaspan substantially earlier than September 20, 2013.

16. Kos and Barr also knew and intended that their Exclusion Payment Agreement would prevent still other generic companies from launching their own generic Niaspan before Barr did, thereby creating a bottleneck. As the first filer of an ANDA for generic Niaspan, Barr is entitled to market its generic Niaspan for 180 days free from competition from other generic Niaspan products. The operation of the Exclusion Payment Agreement between Kos and Barr blocks all other generic Niaspan products from coming to market until 180 days after September 20, 2013 because, absent circumstances discussed below, FDA will not approve subsequently-filed ANDAs until Barr's exclusivity period has run, which will not occur until 180 days after Barr launches.

17. Although it is possible that Barr could forfeit its 180 day exclusivity if it does not begin commercial marketing of its generic Niaspan products within 75 days of a court decision that all of the patents listed in the FDA's book of Approved Drug Products with Therapeutic

Equivalence Evaluations, commonly referred to as the "Orange Book," for Niaspan are invalid or not infringed, Kos made sure that the later ANDA-filers for Niaspan would not break the bottleneck caused by its Exclusion Payment Agreement with Barr by obtaining such a court decision. Before those cases yielded court determinations on the issue of invalidity and/or non-infringement of the Niaspan patents, Abbott, having acquired Kos, settled those suits and those ANDA-filers dropped their patent challenges and agreed to stay out of the market until after Barr is permitted to enter the market under its Exclusion Payment Agreement with Kos.

18. But for the defendants' unlawful Agreement at issue here, generic versions of Niaspan would have entered the market substantially earlier than September 20, 2013. Absent the defendants' illegal Agreements, Professional Drug and the members of the class would have already been able to satisfy their delayed-release niacin requirements at significantly lower prices, rather than being forced to pay high prices for branded Niaspan because of the defendants' illegal agreements in restraint of trade.

19. Defendants' unlawful Exclusion Payment Agreements were designed to and did in fact: (a) preclude the entry of less expensive generic versions of delayed-release niacin in the United States; (b) fix, raise, maintain or stabilize the prices of delayed-release delayed-release niacin products; (c) permit Kos and later Abbott to maintain a monopoly in the United States for delayed-release niacin; and (d) allocate 100% of the United States delayed-release niacin market to Kos and later Abbott.

20. As alleged in more detail below, the defendants violated § 1 and § 2 of the Sherman Act through their conspiracy to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of delayed-release niacin.

JURISDICTION AND VENUE

21. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Professional Drug and members of the class (defined below) resulting from the defendants' unlawful foreclosure of the United States market for delayed-release niacin. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

22. Defendants transact business within this District, and they carry out interstate trade and commerce in substantial part in this district and/or have an agent and/or can be found in this District. Venue is therefore appropriate within this District under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

PARTIES

A. Plaintiff.

23. Plaintiff Professional Drug Company, Inc. ("Professional Drug") is a corporation organized under the laws of the State of Mississippi, with its principal place of business located at 186 Bohn Street, Biloxi, Mississippi 39530. Professional Drug purchases pharmaceuticals directly from manufacturers and then sells them to indirect purchasers. Professional Drug purchased Niaspan directly from one or more of the defendants during the proposed class period and was injured by their anticompetitive conduct.

B. Defendants.

24. 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.

25. 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.

26. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

27. Defendant Teva Pharmaceutical Industries, Ltd., is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva 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.

28. 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.

29. 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.

30. 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.

31. Although not named as a defendant, Kos was one of the initiators of the unlawful

scheme described in this complaint. Kos was a corporation organized under the laws of the state of Florida, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos was merged into Abbott, which became the successor to all of Kos' unlawful conduct described in this complaint.

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

33. All of the defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

REGULATORY BACKGROUND

A. The regulatory structure for approval of generic drugs.

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

35. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list in the "Orange Book" any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents. Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

36. The FDA relies completely on the brand name manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments.

37. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may instead file an abbreviated new drug application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and is absorbed at the same rate and to the same extent as the brand drug – that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug.

38. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having

the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

39. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products.

40. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

2. Paragraph IV Certifications.

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

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

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

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

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

42. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of its ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

43. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months.

44. Brand name manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor

that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to thirty months. That brand-name manufacturers often sue generics under Hatch-Waxman simply to delay generic competition – as opposed to enforcing a valid patent that is actually infringed by the generic – is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

45. The first generic applicant can help the 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 delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck," because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

3. Forfeiture provisions under the MMA.

46. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic pharmaceutical companies to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their products.

47. Under the "failure to market" provision, a first ANDA applicant will forfeit its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that

qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

48. Brand name manufacturers and first-filing generics are able to structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment settling the litigation that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger a forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action over patents that the brand company did not assert against it in a Paragraph IV Litigation.

49. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, *i.e.*, all generics (other than one marketed by the branded manufacturer) are kept off the market for at least six months. For ANDAs with Paragraph IV certifications filed before December, 2003, a first-filer's 180-day exclusivity period will only be triggered upon the earlier of (a) the first-filer's commercial launch, or (b) entry of a final judgment from a court decision of invalidity, unenforceability, or non-infringement. That is, the FDA will not approve any subsequently-filed ANDA until the first-

filer's 180-day exclusivity period has run, which (absent a final judgment on a relevant court decision) will not occur until 180 days after the first-filer launches its product.

B. Background on authorized generics, no-authorized generic agreements, and exclusive licenses.

50. In an increasing number of instances, a brand company can disguise an exclusion payment to a first-filing generic company by agreeing not to launch an "authorized generic" version of the branded drug during the initial 180-day marketing exclusivity period. An authorized generic is the branded drug, manufactured just like the branded product, but sold as a generic product under the same approval as the brand product's original NDA. Because the brand manufacturer already has approval to sell its branded drug, it does not need to file an ANDA, or obtain any additional approvals, to market a chemically identical generic version of the drug.

51. For the brand company, an authorized generic launch during the 180-day period provides a low cost, low risk means to regain some of the revenue lost from the termination of brand exclusivity that would otherwise go to the generic first filer. For the generic manufacturer holding a 180-day exclusivity, however, an authorized generic launch has a substantial negative impact on its revenue. Generic companies generally make about 80 percent of their total income on a given generic product during the 180-day exclusivity period, and an authorized generic, when launched during the 180-day exclusivity period, captures 50% of total generic sales during that period. Freedom from an authorized generic during the initial 180-day period is thus exceedingly valuable to the generic company holding that exclusivity. It doubles the revenues and profits of that generic company.

52. To prevent this 50% loss of revenue from an authorized generic launch, a generic company holding 180-day exclusivity may be willing to delay its entry in return for a brand company's agreement to forego its own revenue stream and forebear from launching an

authorized generic during the 180-day exclusivity period, as Kos and Barr agreed to do here. Although a brand company will lose authorized generic product revenue and profits when making a no-authorized generic agreement, it retains far more in branded profits and sales from paying a generic company to delay market entry using such a no-authorized generic agreement.

53. No-authorized generic agreements can take a variety of forms. Most commonly, they are structured as an "exclusive license," in which the brand company agrees to allow the generic exclusivity to market its generic product during the first-filer's statutory 180-day exclusivity period.

54. In a report by the Federal Trade Commission issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the FTC concluded that no-authorized generic agreements can provide significant value to a first-filer generic company and have become a common form of payment from brands to generics to induce delayed generic entry. The FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition can reduce the first-filer generic's revenues by more than 50 percent during the 180-day exclusivity period. The FTC found that a generic company makes significantly less when competing with an authorized generic because the authorized generic takes a significant share of generic sales away from the first filer, and wholesale and retail prices decrease when the first filer faces an authorized generic.

55. For the first-filer generic, like Barr, of a branded product like Niaspan, the difference between selling the only generic product and competing against an authorized generic during the exclusivity period can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic Report cites numerous documents from industry participants confirming the financial impact of an

authorized generic. No-authorized generic agreements like the one between Kos and Barr thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

C. Generic versions of brand-name drugs are significantly less expensive, and take significant sales directly from the corresponding brand-name versions.

56. Typically, AB-rated generics are priced significantly below their branded counterparts. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted by pharmacists when presented with a prescription for the brand-name counterpart. In particular, generic drugs that are therapeutically equivalent to their brand name counterparts are given an "AB" rating by the FDA. In every state, pharmacists are permitted (and, in some states, required) to substitute a generically-equivalent product for the brand-name product prescribed, unless the doctor has indicated that the prescription for the brand-name product must be "dispensed as written." As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and pharmacy substitution, and thus the loss of sales volume by the brand-name drug to the corresponding generic, accelerates.

57. Generic competition enables all members of the proposed class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales.

58. Consequently, brand-name drug manufacturers have a strong incentive to use

various tactics, including exclusion payment agreements such as the Agreements alleged above and below, to delay the introduction of generic competition into the market.

FACTUAL ALLEGATIONS

A. Defendants' unlawful conduct.

1. Niaspan accounts for the vast majority of Kos' revenues, profits, and market capitalization.

59. Niacin 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 beginning in the 1930s. In proper dosages, niacin will raise levels of HDL cholesterol (the so-called "good" cholesterol) in patients. However, at high levels, niacin causes a patient's skin to flush with redness and it may cause liver toxicity.

60. 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 to boost HDL cholesterol in 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.

61. 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 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. 6,469,035 (the '035 Patent); Patent

No. 6,676,967 (the '967 Patent); Patent No. 6,746,691 (the '691 Patent); Patent No. 6,818,229 (the '229 Patent). In addition, Kos purchased Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

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

63. Over time, Kos submitted the above patents to the FDA for listing in the Orange Book.

64. In September of 1997, Kos went to market with Niaspan, eventually selling Niaspan in dosages of 500 mg, 750 mg, and 1000mg. 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 garnered many millions of dollars of sales.

65. In the early years, nearly all of Kos' Sales Revenue was derived from sales of Niacin, because Kos had no other significant drugs in its portfolio. As the years progressed, 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.

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

66. In the early part of the 2000s, Kos had market power with respect to pricing Niaspan. Indeed, on several occasions during those early tears, 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.

2. Barr poses a competitive threat by preparing to bring a generic equivalent of Niaspan to market.

67. On October 2, 2001, after conducting extensive research and analysis regarding the patents that Kos had registered, conducting extensive legal due diligence concerning potential infringement or invalidity of Kos's patents, and spending over $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.

68. On January 15, 2002, Barr sent Kos 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 first company to file such a certification. As the first ANDA filer, Barr expected that it would someday have an exclusive 180-day period to market its generic equivalent of Niaspan.

69. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring a generic equivalent of Niaspan to market. President and CEO Adrian Adams promised that Kos would "vigorously enforce [its] patent rights in order to protect Kos's cholesterol products, which [Kos has] effectively pioneered entirely on [its] own."

70. 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 that prohibited the FDA from granting Barr Final Approval to launch a generic equivalent of Niaspan.

71. 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 76-738 (with an accompanying a Paragraph IV Certification) with respect to the 500 mg and 750 mg dosages of Niaspan.

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.

Those cases 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, 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. (Congress amended the relevant statute in 2003,

and no lawsuit filed after 2003 would result in a new 30-month stay with respect to the approval of Barr's ANDAs and its proposed generic equivalent of Niaspan.

72. 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 Niaspan.

73. 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.

74. 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.

75. 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 equivalent 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 31, 2005). In this complaint, unless indicated otherwise, "Niaspan" refers to

all of the dosages of the drug.

76. 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.

3. Barr is ready to launch a generic equivalent of Niaspan At-Risk in the Spring of 2005.

77. 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. (In the pharmaceutical industry, a generic launch before the resolution of the patent infringement litigation is called an "At-Risk" launch.) By Spring 2005, Barr was ready and willing, and would have been able, to launch its generic equivalent to Niaspan as soon as the FDA approved Barr's ANDA. Rumors of Barr's anticipated impending At-Risk launch caused Kos' shares to drop 13% in December of 2004.

78. Barr's At-Risk launch would have brought a generic to market in the Spring of 2005, without regard for the strength of the claims in the pending patent lawsuits, and without regard to the expiration dates on any of Kos' patents. No event had occurred that had caused Barr to forfeit its 180-day exclusivity period under applicable law.

79. Kos saw the prospect of an at-risk launch by Barr as a growing competitive threat. Kos acted swiftly in response to Barr's upcoming at-risk launch.

a. Kos began preparing to launch its own authorized generic version of Niaspan, which would deprive Barr of 180 days of exclusivity as the sole generic on the market, and which would replace some of Kos's lost brand revenues with those from authorized generic purchases. Kos began

manufacturing this authorized generic version of Niaspan so that it would have inventory on hand to sell as soon as Barr launched at-risk. By the end of the first quarter of 2005, Kos had accumulated substantial inventory for its authorized generic launch. Kos was prepared to launch – and would have launched – an authorized generic version of Niaspan in early 2005, if Barr had launched its generic version of Niaspan at-risk.

b. 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 generic Niaspan. Barr responded in writing to those papers on March 14, 2005, and Kos filed reply papers on March 16, 2005. The court held a hearing on Kos' application for a preliminary injunction on March 18, 2005.

80. At the time of the March 18th Hearing on Kos' Application for a Preliminary Injunction, Barr was ready to launch its generic equivalent of Niaspan. Barr was accumulating inventory that it would need to fill orders for its generic product as soon as the launch occurred. Barr was waiting for the FDA to issue Final Approval, which Barr expected to receive in April, 2005.

4. Kos and Barr enter into the Exclusion Payment Agreement, agreeing that Barr will not launch a generic competitor to Niaspan for more than eight years.

81. 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. That court issued a Conditional Order of Discontinuance on March 30, 2005.

82. The fact that Barr was ready to launch – and was going to do so in April of 2005 – led Kos to settle the patent litigation in March of 2005. Because Niaspan was so important to Kos' viability and valuation, and because the prospect of an at-risk launch by Barr posed too great a threat to the pricing of Niaspan, Kos needed a way to prevent generic entry so that it could continue to charge higher prices and continue to sell high volumes of Niaspan. Kos and Barr fashioned their Exclusion Payment Agreement in a way that preserved Niaspan's dominant position in the market, while splitting some of the supracompetitive revenues that were the result of that dominant position.

83. Kos and Barr entered into the Exclusion 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 extraordinary revenues that were the result of that dominant position.[1]

84. As part of the Exclusion Payment Agreement, on April 12, 2005, Kos and Barr executed three contracts that facilitated and helped effectuate their unlawful Agreement. Those three contracts were as follows:

a. **Settlement and License Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license of all of the patents arguably covering Niaspan (as listed, above), on the condition that Barr will 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

[1] That agreement also included anticompetitive terms relating to Kos's drug Advicor. Defendants' anticompetitive agreement covering Advicor is memorialized in the same Exclusion Payment Agreement as the Niaspan agreement and incorporates the same key terms – including Barr's agreement not to launch a generic version of Advicor until September 2013 and Kos's agreement not to launch an authorized generic form of Advicor.

exclusively for 180 days). Kos also agreed that it would not launch an authorized generic version of Niaspan despite the fact that Kos had been planning to do so and that it would make economic sense for Kos to launch and authorized generic; of course, the harm to Barr of Kos' launching of an authorized generic would have been substantial. Barr agreed not to launch that generic until September 20, 2013. For a period of years after Barr began selling generic Niaspan and Advicor, for every unit of generic Niacin and Advicor that Barr would sell, Barr agreed to pay a percentage of its profits 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).

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

c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA-approved manufacturing processes for Niaspan and Advicor. Kos (and

Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacturer 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. If Barr sold a generic equivalent of Niaspan to any third-party before September 20, 2013, Kos would have no further obligation to make quarterly payments to Barr.

85. The Exclusion Payment Agreement had 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.

86. On April 12, 2005, and as envisioned by the Exclusion Payment Agreement, the New York court dismissed all of the patent infringement cases that were pending between Barr and Kos regarding Niaspan.

87. Under the Exclusion Payment Agreement, Kos has paid and continues to pay Barr to not launch generic Niaspan until 2013. Those payment take at least the following forms:

a. A lump sum payment, which was disguised a "stand-by" payments to compensate Barr for being ready to manufacture Niaspan under the License and Manufacturing Agreement (when in fact the stand-by payment far exceeded the value that Barr provided to Kos by being ready to manufacture and supply Niaspan);

b. An agreement by Kos not to launch an authorized generic version of Niaspan during Barr's 180-days of exclusivity notwithstanding the facts that:

i. Kos had been planning to launch an authorized generic when faced with Barr's impending At-Risk launch in 2005;

ii. It makes economic sense for Kos to launch an authorized generic during Barr's 180-day exclusivity period so that Kos can retain some of the sales that Barr's less expensive generic seeks to capture and that Kos sacrifices profit by its forbearance;

iii. This agreement not to launch an authorized generic during Barr's 180-day exclusivity period was worth hundreds of millions of dollars to Barr.

c. 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 the quarterly payments far exceeded the value that Barr provided by remaining ready to manufacture and supply Niaspan); and

d. 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 was providing).

88. Because of those payments, Barr has not launched. In the years that have followed, Barr (and its successor) has continued to receive those payments, and Barr (and its successor) has continued with its commitment that it will not launch a generic equivalent of

Niaspan.

89. But for the Exclusion Payment Agreement and the parties' ongoing adherence to that 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 – whether in April 2005 or at any time thereafter – the generic equivalent would have sold at lower prices than the prices at which Kos was selling the brand name version of Niaspan. Professional Drug would have paid lower prices – on both brand name Niaspan and on generic Niaspan – than it otherwise paid.

b. If Kos had launched its authorized generic equivalent of Niaspan in 2005 – or at any time thereafter – 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 Exclusion Payment Agreement prevented that generic competition from occurring and kept prices higher for Plaintiff and the class.

c. If Barr had launched At-Risk in April of 2005, 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.

90. 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.

91. Kos' early payments to Barr under this agreement were substantial, and those payments have continued to involve substantial sums.

a. An "upfront fee" upon signing the settlement agreement in exchange 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 $37.0 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. Kos's and Barr's anticompetitive deal concerning Advicor in the Exclusion Payment Agreement mirrored their deal concerning Niaspan. Kos paid Barr millions of dollars more than it otherwise would have paid.

e. Long after the Exclusion Payment Agreement was assigned following multiple corporate transactions, Kos (and its successors) continued to pay Barr (and its successor), and those payments have involved tens of millions of dollars every year. Those payments are still occurring in 2013.

92. Consistent with the Exclusion Payment Agreement, Kos and Barr took steps to conceal their unlawful agreement to suppress generic competition.

a. When the Exclusion Payment Agreement was announced, 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 Barr would have launched a generic equivalent of Niaspan At-Risk in April of 2005. Thus, when Kos and Barr proclaimed that the Exclusion Payment 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 the Exclusion Payment Agreement was to delay generic entry for more than eight years.

b. When the Exclusion Payment Agreement was announced, Kos and Barr both refused to disclose the amount of the payments provided under the Agreement, 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 delay generic entry for more than eight years.

93. Shortly after the Exclusion Payment Agreement was signed, Barr received the clearance from the FDA that it had been expecting. On April 26, 2005, the FDA issued a letter to Barr, granting final approval to Barr to manufacture and market generic Niaspan.

94. Shortly after the Exclusion Payment Agreement was signed, Barr disposed of its inventory that it had accumulated to be ready for its generic launch, and Barr took an inventory write-down in connection with its decision not to launch in April of 2005. Also, shortly after the Exclusion Payment Agreement, Kos also took a write-down for its generic inventory of a generic version of Niaspan. (Kos had accumulated that inventory prior to the Exclusion Payment Agreement, on the expectation that it would need to begin selling a generic product as soon as Barr launched).

5. Abbott acquires Kos and continues the unlawful agreement to suppress generic competition.

95. 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

that offer, Kos' portfolio of products was still heavily dependent on Niaspan, and Kos had few products in development. Thus, Niaspan (along with the above-described unlawful and ongoing Exclusion Payment Agreement that was keeping Barr from launching a generic equivalent of Niaspan) was a central element of Abbott's valuation of Kos' business. Had generic versions of Niaspan entered the market prior to November 2006, Abbott would have not been willing to pay nearly as much as it ultimately paid for Kos.

96. 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 Exclusion 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 on September 20, 2013, and Abbott continued to make the agreed-upon payments to Barr. In this way, both parties continued with the unlawful Exclusion Payment Agreement that suppressed and continues to suppress generic competition for Niaspan.

97. 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, and instead continued to participate in it.

98. To the extent that the Exclusion Payment Agreement had any minimal lawful value to Kos in the form of co-promotion services or backup supply arrangements, those considerations had even less value to Abbott, because Abbott was large enough to have its own promotion and supply capacity. The Exclusion 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.

99. Because Abbott was a substantially larger enterprise than Kos was, Abbott was

better able to exploit the market advantages created by the ongoing unlawful Exclusion Payment Agreement to suppress generic competition. After Abbott took over the Niaspan business, sales of Niaspan increased significantly. Over the years, U.S. retail sales of Niaspan grew as follows: $474 million in 2006; $546 million in 2007; $639 million in 2008; $717 million in 2009; $794 million in 2010; $1.13 billion in 2011; and $1.03 billion in 2012.

6. Teva acquires Barr and continues the unlawful agreement to suppress generic competition.

100. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to follow the ongoing unlawful Exclusion 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.

101. As a result of its acquisition of Barr, Teva also owned (either directly or indirectly) the first-filer rights held by Barr. Accordingly, no other generic company will be able to could launch a generic equivalent of Niaspan until Teva has had a 180-day period as the exclusive generic seller. If Teva launches a generic equivalent of Niaspan on September 20, 2013, no other generic company can introduce a generic equivalent of Niaspan until March 2014.

102. 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, and instead continued to participate in it.

7. Abbott acts to preserve the unlawful agreement to suppress generic competition.

103. In furtherance of the unlawful and ongoing Exclusion 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.

104. For example, Abbott knew that if any other generic drug manufacturer obtained a final judgment following a court decision of invalidity, unenforceability or non-infringement, then Teva may be motivated to launch its generic product immediately, because Teva's 180-day exclusivity period would begin to run. Such a final judgment on Abbott's patent rights would force Teva to enter the market before the agreed-upon launch dated of September 20, 2013, and the defendants' unlawful scheme would have been cut short. The defendants recognized this risk, and Abbott undertook to avoid such a disruption. 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 who had filed Paragraph IV

Certifications with respect to a possible generic equivalent of Niaspan.[2] Three of those cases have been dismissed by stipulation, with no final judgments entered on the infringement, the validity or the enforceability of Abbott's patents. The other four cases remain pending, and are still in the early stages of discovery, with no final judgments entered on the infringement, the validity, or the enforceability of Abbott's patents.

In all of these lawsuits, Abbott has been able to avoid the entry of any definitive ruling that would disrupt the trigger date for the 180-day exclusivity for Teva. Through delay, and through settlements, Abbott has ensured that no final judgment has been entered on non-infringement, invalidity or unenforceability of the relevant patents.

105. Abbott has prosecuted these patent cases as part of its agreement to take steps that are necessary to preserve the agreement to suppress generic competition, as part of the Exclusion Payment Agreement. Abbott's dilatory conduct in these lawsuits was – and is – part of and in furtherance of its ongoing unlawful Agreement with Teva to suppress generic competition in the market for Niaspan.

8. Abbott spins off Niaspan to AbbVie, and AbbVie continues with the unlawful agreement to suppress generic competition.

106. 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 has stepped into the shoes of Abbott with respect to the ongoing

[2] *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. No. 12-cv-235); *Abbott Laboratories v. Mylan, Inc.* (D. Del. Dkt. No. 12-cv-257); *Abbott Laboratories v. Watson Laboratories, Inc.* (D. Del. Dkt. No. 12-cv-324); *Abbott Laboratories v. Kremers Urban Pharmaceuticals, Inc.* (D. Del. 12-cv-703); *Abbott Laboratories v. Amnael Pharmaceuticals LLC* (D. Del. Dkt. No. 12-cv-1088); and *Abbott Laboratories v. Watson Laboratories, Inc.* (D. Del. 12-cv-1409).

unlawful Exclusion Payment Agreement with Teva. Teva has continued to refrain from launching a generic equivalent of Niaspan, and AbbVie has continued to make the agreed-upon payments to Teva.

107. 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, and instead continued to participate in it.

B. The unlawful agreement to suppress generic competition is ongoing, and it continues to cause injury.

108. As of today, no generic equivalent of Niaspan or Advicor is on the market in the United States. AbbVie continues to sell brand name Niaspan and Advicor at artificially-inflated prices, and Professional Drug has been denied the lower prices that generic competition would have brought to the market. This lack of generic competition is the direct result of the ongoing unlawful Exclusion Payment Agreement that will continue at least through the end of 2013.

109. The unlawful agreement will result in higher prices in another way. In September of 2013, when Teva begins selling generic Niaspan, Teva will charge higher prices than would have been charged but for the Exclusion Payment Agreement, because Teva has an Agreement with AbbVie that both companies will share the profits from Teva's sales of a generic equivalent of Niaspan. To allow for that profit sharing, Teva will launch its generic at a higher price than it otherwise would have. Additionally, by virtue of Kos' unlawful agreement not to launch an authorized generic during Barr's 180-days of exclusivity, Teva would not have faced competition from other generic versions of Niaspan during the most lucrative time immediately following Teva's launch.

110. During the four-year period prior to the filing of this complaint, the defendants'

unlawful conduct has been ongoing and the plaintiff has continued to suffered injury every day that the defendants' unlawful Exclusion Payment Agreement not to compete has remained in place. During the applicable limitations period, the defendants have operated under an ongoing Exclusion Payment Agreement to suppress generic competition, and Professional Drug has been injured by the defendants' conduct.

C. The unlawful agreement to suppress generic competition harms competition, injures the plaintiff, and causes damages.

111. 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 then. 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 then. That is, the FDA issues Tentative Approval only when it determines that an ANDA would otherwise be ready for final approval but for a 30-month stay.

112. But for the defendants' overarching, anticompetitive and ongoing scheme to delay generic Niaspan competition in the United States, a generic equivalent of Niaspan would have been available in the United States far earlier than September 20, 2013 (which is the first date that a generic product is likely to become available).

113. Additionally, but for the illegal conduct described in the complaint, Kos would have launched its own authorized generic Niaspan product at the same time that Barr launched, resulting in additional price competition for Niaspan during Barr's 180-day exclusivity period.

114. But for the anticompetitive, illegal and ongoing conduct alleged in this complaint, plaintiff 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 Professional Drug and the class by causing them to pay substantial overcharges – potentially hundreds of millions of dollars – on their purchases of Niaspan.

115. The active ingredient in Niaspan is extended-release niacin. Its pharmacological profile, and thus its side effect and efficacy profile, is different than other prescription and non-prescription medicines that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Niaspan, cannot be automatically substituted for Niaspan by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Niaspan, and thus are not economic substitutes for, nor reasonably interchangeable with, Niaspan.

CLASS ACTION ALLEGATIONS

116. Professional Drug brings this action on behalf of itself and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States who purchased branded Niaspan directly from any of the defendants at any time during the period April 3, 2009, through the date that the anticompetitive effects of the defendants' challenged conduct cease.

Excluded from the class are the defendants, their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

117. Members of the class are so numerous that joinder is impracticable. Professional Drug believes that the class numbers in the tens at least and is geographically spread across the nation. Further, the class is readily identifiable from information and records in the possession of the defendants.

118. Professional Drug's claims are typical of the claims of the members of the class. Professional Drug and all members of the class were damaged by the same wrongful conduct by defendants, *i.e.,* they paid artificially inflated prices for delayed-release niacin and were deprived the benefits of competition from less-expensive generic versions of Niaspan as a result of the defendants' wrongful conduct.

119. Professional Drug will fairly and adequately protect and represent the interests of

the class. Professional Drug's interests are coincident with, and not antagonistic to, those of the class.

120. Professional Drug is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

121. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

122. Questions of law and fact common to the class include:

a. whether, the defendants conspired to suppress generic competition to Niaspan;

b. whether, pursuant to the Agreement, the Barr agreed to delay its entry into the market with generic Niaspan;

c. whether, pursuant to the Agreement, Kos compensated the Barr;

d. whether Kos's compensation to Barr was for a purpose other than delayed entry of generic Niaspan;

e. whether Kos's compensation to Barr was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

f. whether the Agreement created a bottleneck to generic competition;

g. whether the Agreement is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;

h. whether the defendants' challenged conduct suppressed generic competition to Niaspan;

i. whether the defendants' challenged conduct harmed competition in the market(s) in which Niaspan is sold;

j. whether Kos possessed market or monopoly power over Niaspan;

k. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

l. whether the activities of the defendants as alleged herein have substantially affected interstate commerce;

m. whether, and to what extent, the defendants' conduct caused antitrust injury to the business or property of plaintiff and the members of the class in the nature of overcharges; and

n. the quantum of overcharges paid by the class in the aggregate.

123. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

124. Professional Drug knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

INTERSTATE COMMERCE

125. At all material times, Kos and later Abbott manufactured, promoted, distributed, and sold substantial amounts of Niaspan in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

126. At all material times, the defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and

uninterrupted flow of commerce across state and national lines in connection with the sale of Niaspan and/or AB-rated bioequivalents.

127. In furtherance of their efforts to monopolize and restrain competition in the market for delayed-release niacin, the defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of the defendants were within the flow of and have substantially affected interstate commerce.

MONOPOLY POWER AND MARKET DEFINITION

128. At all relevant times, Kos and later Abbott had monopoly power over delayed-release niacin because it had the power to maintain the price of the drug it sold as Niaspan at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Niaspan, with the exception of AB-rated generic versions of Niaspan.

129. A small but significant, non-transitory price increase for Niaspan by Kos and later Abbott would not have caused a significant loss of sales.

130. Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Niaspan.

131. Because of its labeling, Niaspan is differentiated from all products other than AB-rated generic versions of Niaspan.

132. Kos and later Abbott needed to control only Niaspan and its AB-rated generic equivalents, and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Niaspan would render Kos and later Abbott unable to profitably maintain its current prices of Niaspan without losing substantial sales.

133. Kos and later Abbott also sold Niaspan at prices well in excess of marginal costs,

and in excess of the competitive price, and enjoyed high profit margins.

134. Defendants have had, and exercised, the power to exclude and restrict competition to Niaspan and AB-rated bioequivalents.

135. Kos and later Abbott at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

136. Professional Drug alleges that the relevant market is delayed-release niacin (*i.e.*, Niaspan and its AB-rated generic equivalents). During the period relevant to this case, Kos and later Abbott has been able to profitably maintain the price of delayed-release niacin well above competitive levels.

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

138. At all relevant times, Kos' and later Abbott's market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

EFFECTS ON COMPETITION, AND THE DAMAGES CLAIMED IN THIS ACTION

139. Barr's ANDA was in finally approved on April 26, 2005. Were it not for the Kos/Barr Agreement, generic Niaspan products would have entered the market before September 20, 2013.

140. Defendants' Exclusion Payment Agreements have delayed generic competition and unlawfully enabled Kos and later Abbott to sell Niaspan without generic competition. But for the defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Niaspan substantially earlier than September 20, 2013.

141. The generic manufacturers seeking to sell generic Niaspan had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs,

marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

142. Defendants' Exclusion Payment Agreements, which delayed introduction into the United States marketplace of generic versions of Niaspan, have caused Professional Drug and the class to pay more than they would have paid for delayed-release niacin absent the defendants' illegal conduct.

143. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of branded drugs are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more to the generics.

144. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name 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.

145. But for the Exclusion Payment Agreements, direct purchasers, such as Professional Drug and members of the class, would have paid less for delayed-release niacin by (a) substituting purchases of less-expensive AB-rated generic Niaspan for their purchases of more-expensive branded Niaspan, (b) receiving discounts on their remaining branded Niaspan purchases, and (c) purchasing generic Niaspan at lower prices sooner.

146. Moreover, due to the defendants' Exclusion Payment Agreement, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Niaspan, and/or (b) challenging the validity or infringement of the Niaspan patents in court.

147. As discussed above, but for the Exclusion Payment Agreement, Kos would have launched its own authorized generic Niaspan product during Barr's 180-day exclusivity period, resulting in additional price competition for Niaspan.

148. Thus, the defendants' unlawful conduct deprived Professional Drug and the class of the benefits of competition that the antitrust laws were designed to ensure.

149. During the relevant period, Professional Drug and other members of the class purchased substantial amounts of Niaspan directly from Kos and later Abbott. As a result of the defendants' illegal Exclusion Payment Agreements as alleged herein, Professional Drug and other members of the class were compelled to pay, and did pay, artificially inflated prices for their delayed-release niacin requirements. Professional Drug and the other class members paid prices for delayed-release niacin that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic Niaspan instead of expensive brand-name Niaspan; (2) class members paid artificially inflated prices for delayed-release niacin.

150. As a consequence, Professional Drug and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

151. This complaint alleges a continuing course of conduct (including conduct within the limitations period), and Professional Drug and the mem

CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2
(Conspiracy to Monopolize)

152. Professional Drug hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

153. At all relevant times, Kos and later Abbott possessed substantial market power (*i.e.*, monopoly power). They possessed the power to control prices in, prevent prices from falling in, and exclude competitors.

154. Through the Exclusion Payment Agreement with Barr, Kos conspired to maintain Kos's monopoly power in the relevant market in order to block and delay market entry of delayed-release niacin, *i.e.*, AB-rated generic versions of Niaspan. The unlawful Exclusion Payment Agreement between Kos and Barr allocated all sales of delayed-release niacin in the United States to Kos; delayed the sales of generic Niaspan products; and fixed the price at which Professional Drug and members of the class would pay for delayed-release niacin at the higher, branded price.

155. The goal, purpose and/or effect of the Exclusion Payment Agreement was to maintain and extend Kos's monopoly power in the United States market for delayed-release niacin in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and/or delayed generic competition to Niaspan and enabled Kos to continue charging supracompetitive prices for Niaspan without a substantial loss of sales.

156. Kos and Barr knowingly and intentionally conspired to maintain and enhance Kos's monopoly power in the relevant market.

157. Kos and Barr specifically intended that their Exclusion Payment Agreement

would maintain Kos's monopoly power in the relevant market, and injured Professional Drug and the class thereby.

158. Kos and Barr each committed at least one overt act in furtherance of the conspiracy.

159. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, Professional Drug and the class were harmed.

CLAIM II: VIOLATION OF 15 U.S.C. § 1
(Agreement Restraining Trade)

160. Professional Drug hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

161. In or about April 2005, and at times prior to the formal execution thereof, Kos and Barr entered into the Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Kos agreed to pay Barr substantial consideration in exchange for Barr's agreement to delay bringing its generic version of Niaspan to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release niacin in the United States to Kos; (b) prevent the sale of generic versions of Niaspan in the United States, thereby protecting Niaspan from any generic competition until September 20, 2013; and (c) fix the price at which direct purchasers would pay for delayed-release niacin at supracompetitive levels.

162. The Agreement harmed Professional Drug and the class as set forth above.

163. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

164. Kos and Barr are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

165. There is and was no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payment that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve such a purpose.

166. As a direct and proximate result of Kos's and Barr's anticompetitive conduct, as alleged herein, Professional Drug and the class were harmed as aforesaid.

DEMAND FOR JUDGMENT

WHEREFORE, Professional Drug, on behalf of itself and the class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare Professional Drug as the representative of the class;

B. Enter joint and several judgments against the defendants and in favor of Professional Drug and the class;

C. Adjudge the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be an unlawful restraint of trade in violation of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

D. Permanently enjoin the defendants pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26, from continuing their unlawful contact, so as to assure that similar anticompetitive conduct does not continue to occur in the future;

E. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

F. Award Professional Drug and the class their costs of suit, including reasonable attorneys' fees as provided by law.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, Professional Drug, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Respectfully submitted,

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