UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PROFESSIONAL DRUG COMPANY, INC., on behalf of itself and all others similarly situated,	:	
Plaintiff,	:	Civil Action No.
v.	:	CLASS ACTION
ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., RANBAXY LABORATORIES, LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA USA, INC., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES, INC.,	:	JURY TRIAL DEMANDED
Defendants.	:	

COMPLAINT

Plaintiff, Professional Drug Company, Inc. ("PDC"), on behalf of itself and all others similarly situated, for its complaint against Defendants AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP (collectively, "AstraZeneca"), Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories Ltd. (collectively, "Ranbaxy"), Teva Pharmaceutical Industries, Ltd., Teva USA, Inc. (collectively, "Teva"), Dr. Reddy's Laboratories Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") (together the "Generic Defendants" or simply the "Generics," and together with AstraZeneca, the "Defendants") alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

I. 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 delayed-release esomeprazole magnesium, sold by AstraZeneca under the brand name Nexium. Nexium is a

proton pump inhibitor prescribed to patients for the healing of erosive esophagitis, maintenance of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease.

2. To protect its over $3 billion in annual Nexium sales from the threat of generic competition, AstraZeneca entered into non-competition agreements with each of the Generic Defendants, agreeing to pay the Generic Defendants substantial sums in exchange for their agreement to delay marketing their less expensive generic versions of Nexium for as many as six years or more, *i.e.*, until May 27, 2014 (the "Exclusion Payment Agreements" or simply the "Agreements"). The Generic Defendants did, in fact, delay marketing their less-expensive versions of Nexium; but for the Agreements, generic versions of Nexium would have been marketed in the United States as early as April 14, 2008, when the 30-month stay of FDA approval of Ranbaxy's generic Nexium product expired.

3. 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 AstraZeneca. 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. In order to delay the drastic loss of its monopoly profits from Nexium, AstraZeneca

engineered a scheme whereby it would buy its way out of competition with the Generic Defendants and mitigate the likelihood that its Nexium patents would be invalidated. Specifically, AstraZeneca agreed to pay the Generic Defendants to defer entering the market until May 27, 2014 and to drop their challenges to the Nexium patents. AstraZeneca and the Generic Defendants attempted to disguise these payments to the Generic Defendants (frequently called "Exclusion Payments" or "Reverse Payments") as payments to compensate them for supplying AstraZeneca with a portion of its Nexium supply, including esomeprazole magnesium, the active pharmaceutical ingredient ("API") in Nexium, for distributing authorized generic versions of two other AstraZeneca drugs, felodipine capsules (brand name, Plendil) and 40 mg omeprazole tablets (brand name, Prilosec) (with respect to Ranbaxy); or (ii) forgiveness of a contingent liability (with respect to Teva and Dr. Reddy's). Defendants intentionally concealed the true purpose and nature of their exclusion payments in an attempt to escape liability under the antitrust laws.

6. Although the Exclusion Payment Agreements purported to settle patent infringement suits that AstraZeneca filed against the Generic Defendants with respect to patents that purportedly cover Nexium, AstraZeneca used the strength of its wallet as opposed to the strength of its patents to obtain the agreement of the Generic Defendants not to launch their generic Nexium products. In light of the substantial possibility that AstraZeneca's Nexium patents would be invalidated and/or that the Generics' products would be adjudged non-infringing—in which case AstraZeneca would have been unable to keep generic versions of Nexium from swiftly eradicating the vast majority of sales from Nexium—AstraZeneca agreed to share its monopoly rents with the Generic Defendants as the *quid pro quo* for the Generic Defendants' agreement not to compete with AstraZeneca in the delayed-release esomeprazole magnesium market until May 27, 2014.

7. Like AstraZeneca, the Generic Defendants knew that it would be more profitable to be paid not to compete than to enter the market. Had the Generic Defendants all launched generic versions of Nexium, as they were preparing and poised to do, the competition among them would have driven down the price of generic Nexium. 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 more profitable to be paid by the brand company not to compete. The Generic Defendants were well aware of these market dynamics, and knew that, rather than entering the market and competing, they could make more profit by agreeing to delay entry in exchange for a portion of AstraZeneca's monopoly profits from Nexium, paid in the form of an Exclusion Payment. And that is precisely what happened.

8. AstraZeneca and Ranbaxy also knew and intended that their Exclusion Payment Agreement would prevent still other generic companies from launching their own generic Nexium before Ranbaxy did, thereby creating a bottleneck. As the first filer of an ANDA for generic Nexium, Ranbaxy is entitled to market its generic Nexium for 180 days free from competition from other generic Nexium products. The operation of the Exclusion Payment Agreement between AstraZeneca and Ranbaxy blocks all other generic Nexium products from coming to market until 180 days after May 27, 2014 because, absent circumstances discussed below, FDA will not approve subsequently-filed ANDAs until Ranbaxy's exclusivity period has run, which will not occur until 180 days after Ranbaxy launches.

9. Although it is possible that Ranbaxy could forfeit its 180 day exclusivity if it does not begin commercial marketing of its generic Nexium 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 Nexium are invalid or

not infringed, AstraZeneca made sure that the second and third ANDA-filers for Nexium—Teva and Dr. Reddy's—would not break the bottleneck caused by its Exclusion Payment Agreement with Ranbaxy by obtaining such a court decision. When Teva and Dr. Reddy's neared a court determination on the issue of invalidity and/or non-infringement of the Nexium patents, AstraZeneca paid them, too, pursuant to the Exclusion Payment Agreements, to drop their patent challenges and stay out of the market until after Ranbaxy was permitted to enter the market under Ranbaxy's Exclusion Payment Agreement with AstraZeneca.

10. But for one or more of the unlawful Agreements at issue here, generic versions of Nexium would have entered the market as early as April 14, 2008, once the 30-month stay of FDA approval of Ranbaxy's generic Nexium products expired. FDA granted tentative approval to Ranbaxy's generic Nexium products on February 5, 2008, which, absent the illegal Agreements complained of herein, would have been converted to a final approval on or about April 14, 2008. Thus, absent Defendants' illegal Agreements, Plaintiff and the members of the Class would have already been able to satisfy their delayed-release esomeprazole magnesium requirements at significantly lower prices, rather than being forced to pay high prices for branded Nexium because of Defendants' illegal agreements in restraint of trade.

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

12. As alleged in more detail below, 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 esomeprazole magnesium.

II. JURISDICTION AND VENUE

13. 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 Plaintiff and members of the Class (defined below) resulting from Defendants' unlawful foreclosure of the United States market for delayed-release esomeprazole magnesium. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

14. 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).

III. PARTIES

A. Plaintiff

15. Plaintiff Professional Drug Company, Inc. ("PDC" or "Plaintiff") is a corporation organized under the laws of the State of Mississippi that purchases pharmaceuticals directly from manufacturers and resells them at wholesale prices to indirect purchasers. Professional Drug's principal place of business is 186 Bohn Street, Biloxi, Mississippi 39530. During the class period, as defined below, PDC purchased branded Nexium directly from AstraZeneca (and will purchase generic Nexium directly from one or more of the Generic Defendants), and was injured as a result of Defendants' unlawful conduct.

B. Defendants

16. Defendant AstraZeneca AB is a company organized and existing under the laws of

Sweden, having its principal place of business in Sodertalje, Sweden.

17. Defendant Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business in Mölndal, Sweden.

18. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business in Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the FDA for a delayed-release esomeprazole magnesium formulation that it sells throughout the United States under the brand name Nexium.

19. Defendant Ranbaxy Pharmaceuticals, Inc., is a company organized and existing under the laws of Florida, with its principal place of business at 9431 Florida Mining Blvd. East, Jacksonville, Florida, and having its place of business at 600 College Road East, Suite 2100, Princeton, New Jersey. This defendant is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

20. Defendant Ranbaxy Laboratories Limited is a public limited liability company organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India.

21. Defendant Ranbaxy, Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

22. Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. (collectively, “Ranbaxy”) are engaged in the worldwide marketing, production and distribution of generic pharmaceutical products.

23. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation having its principal place of business at 5 Basel St, P.O. Box. 3190, Petach Tikva 49131, Israel.

24. 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.

25. Defendants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") are the largest generic manufacturers of pharmaceuticals in the world.

26. Defendant Dr. Reddy's Laboratories, Ltd. is an Indian pharmaceutical company with its principal place of business at Door No 8-2-337, Road No 3, Banjara Hills, Hyderabad – 500034, Andhra Pradesh India.

27. Defendant Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business at 200 Somerset Corp. Blvd., Bridgewater, New Jersey. On information and belief Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. Both entities are referred to collectively herein as "Dr. Reddy's."

28. All of 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 Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of 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 Defendants.

IV. CLASS ACTION ALLEGATIONS

29. Plaintiff 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 and/or generic Nexium directly from any of the Defendants at any time during the period April 14, 2008, through the date the anticompetitive effects of Defendants' challenged conduct cease (the "Class").

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

30. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in the hundreds. Further, the Class is readily identifiable from information and records in the possession of Defendants.

31. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff 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 esomeprazole magnesium and were deprived of the benefits of competition from less-expensive generic versions of Nexium as a result of Defendants' wrongful conduct.

32. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

33. Plaintiff 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.

34. 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 Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

35. Questions of law and fact common to the Class include: a. whether Defendants conspired to suppress generic competition to Nexium;

b. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic Nexium;

c. whether, pursuant to the Agreements, AstraZeneca compensated the Generic Defendants;

d. whether AstraZeneca's compensation to the Generic Defendants was for a purpose other than delayed entry of generic Nexium;

e. whether AstraZeneca's compensation to the Generic Defendants was necessary

to yield some procompetitive benefit that is cognizable and non-pretextual;

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

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

h. whether Defendants' challenged conduct suppressed generic competition to Nexium;

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

j. whether AstraZeneca possessed market or monopoly power over Nexium;

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 Defendants as alleged herein have substantially affected interstate commerce;

m. whether, and to what extent, 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.

36. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such 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.

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

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

38. 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).

39. 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).

40. 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

41. 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.

42. 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).

43. 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.

44. 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

45. 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").

46. 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.

47. 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.

48. 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.

49. 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

50. 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.

51. 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.

52. 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.

B. Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions

53. 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. 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. 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.

VI. FACTUAL ALLEGATIONS

A. Defendants' Unlawful Conduct

1. AstraZeneca Files Paragraph IV Litigation Against the Generic Defendants

54. Nexium is a prescription proton pump inhibitor (PPI) used to treat heartburn and related conditions. The active ingredient in Nexium is esomeprazole magnesium. Its pharmacological profile, and thus its side effect and efficacy profile, is different than other PPIs, H2 blockers and non-prescription antacids that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Nexium, cannot be automatically substituted for Nexium by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Nexium, and thus are not economic substitutes for, nor reasonably interchangeable with, Nexium.

55. On December 3, 1999, AstraZeneca submitted NDA 21-153 seeking FDA approval to market esomeprazole magnesium delayed-release capsules in 20 mg and 40 mg strengths under the brand name Nexium for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease. The FDA approved AstraZeneca's NDA for Nexium on February 20, 2001.

56. In connection with its Nexium NDA, AstraZeneca listed at least thirteen patents in the FDA Orange Book as covering Nexium or a method of using Nexium (the "Nexium patents"). Although the Nexium patents purport to cover, among other things, compounds and pharmaceutical compositions comprised of magnesium salts of esomeprazole, and methods of using those compounds and compositions, there existed a substantial risk that the patents would be invalidated upon a challenge from generic manufacturers.

57. Among other reasons, the Nexium patents are inherently weak because the

esomeprazole "invention" described in the various Nexium patents is *prima facie* obvious in light of the prior art, including, but not limited to, AstraZeneca's prior PPI drug, Prilosec.

58. The active ingredient in Prilosec is omeprazole. Omeprazole is a "racemate," which is a substance consisting of equal parts of two different isomers of the same molecule. The different isomers, known as "enantiomers," are non-superimposable mirror images of one another but are otherwise identical. Human hands are commonly used to illustrate this principle. A person's left hand and right hand are non-superimposable mirror images of each other. Pairs of enantiomers share many chemical and physical properties, though they may exhibit very different biologic activity. For example, it is commonly known that one enantiomer of the pair will be more biologically active than the other.

59. A 20 mg dose of the racemate omeprazole contains 10 mg of the left-handed or "S" (for *sinister*, the Latin word for "left-handed") enantiomer and 10 mg of the right-handed or "R" enantiomer. Nexium, which contains esomeprazole, the S-enantiomer of omeprazole, is simply Prilosec without the less active R-enantiomer.

60. Under well-settled patent law principles, in the case of chemical compounds where the prior art is close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives of the prior art compound, like enantiomers, there arises a presumption of obviousness, *i.e.*, a *prima facie* case of obviousness. Accordingly, enantiomers like Nexium are frequently assumed to be *prima facie* obvious in light of their racemates, shifting the burden to the patentee to establish validity.

61. AstraZeneca faced substantial risk that its Nexium patents would be invalidated through patent litigation. In fact, the European Patent Office has ruled, first in 2006 and then again in 2011, in connection with opposition proceedings brought by generic manufacturers, including at least Generic Defendant Teva, that two European Nexium patents—which are

similar to U.S. Nexium patents—were not just presumed to be invalid, but actually were invalid and thus revoked for failing to satisfy the "inventive step" requirement, which is analogous to obviousness under U.S. patent law.

62. Because the Nexium patents are particularly susceptible to attack on validity grounds, generic companies were eager to apply for FDA approval to market generic versions of Nexium prior to the expiration of the Nexium patents.

63. On or about October 14, 2005, Generic Defendant Ranbaxy notified AstraZeneca that it had filed ANDA No. 77-830, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Nexium product would not infringe any valid claim of any patent that expired after October 2007 listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

64. On November 21, 2005, AstraZeneca filed suit against Ranbaxy in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Ranbaxy's generic Nexium product would infringe six patents, five of which were Orange Book-listed: U.S. Patent No. 5,714,504 (the "'504 Patent"); U.S. Patent No. 5,877,192 (the "'192 patent); U.S. Patent No. 6,875,872 (the "'872 patent"); U.S. Patent No. 6,428,810 (the "'810 patent"); U.S. Patent No. 6,369,085 (the "'085 patent"); and U.S. Patent No. 5,948,789 (the "'789 patent").

65. On or about January 26, 2006, Generic Defendant Teva notified AstraZeneca that it had filed ANDA No. 78-003, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of any patent listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

66. On March 8, 2006, AstraZeneca filed suit against Teva in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Teva's generic Nexium product would infringe five of the patents listed in the Orange Book for Nexium: the '504; '192; '872; '810, and '085 patents. Subsequently, AstraZeneca amended its complaint by dropping its allegation that Teva infringed the '810 patent and adding an allegation that Teva infringed the '789 patent and U.S. Patent No. 7,411,070 (the "'070 patent").

67. On August 17, 2006, Generic Defendant Dr. Reddy's notified AstraZeneca that it had filed ANDA No. 78-279, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Dr. Reddy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of seven of the thirteen Orange Book-listed patents, including the '085 and the '810 patents. On December 4, 2007, Dr. Reddy's amended its ANDA to assert that its proposed generic Nexium product would not infringe the '504, '192 or '872 patents, or that those patents were invalid.

68. On January 17, 2008, AstraZeneca filed suit against Dr. Reddy's in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Dr. Reddy's generic Nexium product would infringe three of the patents listed in the Orange Book for Nexium: the '504; '872; and '085 patents. In reply to Dr. Reddy's answer, AstraZeneca also asserted that Dr. Reddy's proposed generic Nexium product would infringe the '192 patent.

69. AstraZeneca's actions against the Generic Defendants were consolidated, and the Generic Defendants conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the Nexium patents; (2) the validity of the Nexium patents' claims; and (3) the strength of AstraZeneca's infringement allegations. AstraZeneca and the Generic Defendants entered into the Exclusion Payment Agreements before any dispositive motions relating to the

Generic Defendants' substantive challenges to the patents were decided.

70. To prevent generic entry using just its patents (rather than pay-offs), AstraZeneca would have had to show that each of the generic Nexium products infringed its patents and to defeat each of the generic companies' invalidity arguments. AstraZeneca instead decided to protect its monopoly by paying all of the Generic Defendants to withdraw their challenges to the validity and enforceability of its patents and delay their introduction of generic Nexium. And that is precisely what it has done, in concert with the Generic Defendants.

2. AstraZeneca and Ranbaxy Enter an Exclusion Payment Agreement

71. On or about April 14, 2008, shortly after discovery ended and before the court could issue any substantive rulings, AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement. Pursuant to that Agreement, AstraZeneca ended its litigation against first-filer Ranbaxy, and a consent judgment was entered on the exact same day that the 30-month stay of FDA approval of Ranbaxy's generic Nexium product expired.

72. Under the Exclusion Payment Agreement, Ranbaxy agreed to (a) admit that the '504, '192, '789, '085, '810 and '872 patents were enforceable and valid; (b) admit that its generic Nexium products would infringe the '504, '192, '789 and '872 patents (but not the '810 or '085 patents); and (c) delay launching its generic Nexium product until May 27, 2014 unless otherwise specifically authorized by the Agreement.

73. As the *quid pro quo* for Ranbaxy's agreement to drop its challenge to the Nexium patents listed above and to delay entry of its generic Nexium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Ranbaxy hundreds of millions of dollars.

74. Shortly after the settlement, Ranbaxy's Chief Executive Officer, Malvinder Singh, boasted that the Agreement would give Ranbaxy as much as *$1.5 billion* in revenue between the date of the Agreement and the end of its 180-day marketing exclusivity in 2014. Singh

characterized the Agreement as "the biggest and most comprehensive settlement to date by any generic company globally." Upon information and belief, AstraZeneca has already paid Ranbaxy millions of dollars under their Agreement.

75. Although AstraZeneca's payments to Ranbaxy under the Agreement are characterized as payments for Ranbaxy's performance of manufacturing and distribution services for AstraZeneca, those characterizations are pretextual. In fact, the payments from AstraZeneca to Ranbaxy were for Ranbaxy's agreement to delay generic competition to Nexium for over 6 years. Absent Ranbaxy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have agreed to designate Ranbaxy as a supplier of Nexium and Nexium API or as the authorized generic distributor for Plendil or Prilosec and/or would not have agreed to the price and/or terms that it did under those provisions of the Agreement. AstraZeneca paid Ranbaxy for delayed market entry of generic Nexium.

3. AstraZeneca Enters Exclusion Payment Agreements with Teva and Dr. Reddy's to Strengthen the Bottleneck Created by the AstraZeneca/Ranbaxy Exclusion Payment Agreement

76. On April 30, 2008, shortly after AstraZeneca and Ranbaxy entered their Agreement, Generic Defendant Teva filed a declaratory judgment action against AstraZeneca seeking a ruling of invalidity and non-infringement regarding the remaining Orange Book-listed patents that AstraZeneca did not sue Teva for infringing in connection with Teva's generic Nexium ANDA. Teva filed its declaratory judgment action in an attempt to obtain a favorable judgment regarding all Orange Book-listed Nexium patents and thus uncork the FDA approval bottleneck caused by AstraZeneca's settlement with first-filer Ranbaxy, which (absent some other forfeiture event) ensures that Ranbaxy will not trigger its 180-day marketing exclusivity until May 27, 2014. Dr. Reddy's followed in May 2008 with its own declaratory judgment action seeking a ruling of non-infringement with respect to the unasserted Orange Book-listed patents.

77. In response to AstraZeneca's motion to dismiss its declaratory judgment action for lack of jurisdiction, Teva accused AstraZeneca of gaming the system "to take advantage of what [Teva] contends is an *invalid and illegitimate patent monopoly*." According to Teva, as a result of the exclusion payment agreement between AstraZeneca and Ranbaxy, if it could not "challenge the patents in suit, the patents will represent a six-year barrier to anyone entering the market, regardless of whether they are valid or would be infringed. In those circumstances, [Teva] would be precluded from marketing its product and the public would not have access to lower-priced esomeprazole *even though no legitimate patent rights protect defendants' monopoly*."

78. The court denied in substantial part AstraZeneca's motion to dismiss the declaratory actions, but granted AstraZeneca's motion to stay the declaratory actions pending resolution of the main infringement action. Although on reconsideration the court permitted the declaratory actions to proceed, AstraZeneca succeeded in delaying by approximately six months Teva's and Dr. Reddy's efforts to obtain a court judgment that could allow them to enter the market ahead of May 27, 2014.

a. AstraZeneca and Teva Enter an Exclusion Payment Agreement

79. In the interim, Teva and AstraZeneca entered into the AstraZeneca/Teva Agreement. Although claim construction was briefed during the summer of 2009, AstraZeneca and Teva, pursuant to that Agreement, repeatedly asked the court to postpone construing the contested claims of the Nexium patents. The protracted delay meant that the court had issued no substantive rulings as of January 7, 2010. On or about that date, AstraZeneca and Teva entered into the AstraZeneca/Teva Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Teva.

80. Under the Exclusion Payment Agreement, Teva agreed to: (a) admit that all patents then listed in the Orange Book as covering Nexium "are all enforceable and valid with respect to certain products;" (b) admit that its generic Nexium product would infringe the '504, '192, '789, '085, '872 and '070 patents; and (c) delay launching its generic Nexium until May 27, 2014 unless otherwise specifically authorized by the Agreement.

81. As the *quid pro quo* for Teva's agreement to drop its challenge to the Nexium patents and to delay entry of its generic Nexium products until May 27, 2014, pursuant to the AstraZeneca/Teva Exclusion Payment Agreement, AstraZeneca agreed to pay Teva. That payment came in the form of AstraZeneca's forgiveness of Teva from a contingent liability.

82. Teva had an enormous contingent liability to AstraZeneca. On September 9, 2004, Teva had commenced an "at risk" launch of generic Prilosec, which was manufactured by its marketing partner, Impax. In 2008, the Federal Circuit affirmed the district court's ruling that the Prilosec patents were valid and infringed by Impax's generic Prilosec product. Because Teva and Impax shared the risk with respect to any damages associated with the sale of the generic Prilosec product, there was substantial risk that Teva would owe AstraZeneca potentially massive infringement damages resulting from years of infringing generic Prilosec sales. As part of their Exclusion Payment Agreement, Teva and AstraZeneca agreed that Teva would pay only an amount that AstraZeneca characterized as not financially material to account for Teva's past infringing Prilosec sales. By forgiving the substantial part of Teva's contingent liability to it with respect to a different drug, AstraZeneca paid Teva.

83. The true purpose and effect of the payment to Teva was to delay generic competition to Nexium until May 27, 2014. Absent Teva's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Teva substantially all of the contingent liability and/or would not have done so on the terms that it did. AstraZeneca paid

Teva for delayed market entry of generic Nexium.

b. AstraZeneca and Dr. Reddy's Enter an Exclusion Payment Agreement

84. On or about January 28, 2011, before the court could issue any dispositive decision regarding the validity or infringement of the Nexium patents, AstraZeneca and Dr. Reddy's entered the AstraZeneca/Dr. Reddy's Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Dr. Reddy's and delayed entry of Dr. Reddy's generic Nexium products until May 27, 2014 unless specifically authorized by the Agreement. Dr. Reddy's made no admissions regarding validity or infringement.

85. As the *quid pro quo* for Dr. Reddy's agreement to drop its challenge to the Nexium patents and to stay out of the Nexium market until May 27, 2014, AstraZeneca agreed to pay Dr. Reddy's by forgiving Dr. Reddy's from an outstanding contingent liability.

86. Dr. Reddy's had a substantial contingent liability to AstraZeneca. Dr. Reddy's had launched its generic version of AstraZeneca's Accolate product "at risk" in November of 2010, following a summary judgment opinion in Dr. Reddy's favor that AstraZeneca had appealed at the time of the Agreement. By agreeing, as part of and simultaneously with the Exclusion Payment Agreement, to drop its appeal and thereby remove the risk that Dr. Reddy's would have to pay substantial damages with respect to its generic Accolate sales, AstraZeneca paid Dr. Reddy's under the Agreement.

87. The true purpose and effect of the payment to Dr. Reddy's was to delay generic competition to Nexium until May 27, 2014. Absent Dr. Reddy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Dr. Reddy's of the contingent liability against it and/or would not have done so on the terms that it did. AstraZeneca paid Dr. Reddy's for delayed market entry of generic Nexium.

88. By paying Teva and Dr. Reddy's not to market their generic Nexium products before May 27, 2014, and by doing so before the court could rule on the validity or infringement of the Nexium patents, AstraZeneca ensured that the second and third ANDA-filers could not dislodge the FDA approval bottleneck created by its Agreement with first-filer Ranbaxy.

B. Anticompetitive Purpose and Effect of the Agreements

89. The agreements have enabled AstraZeneca and the Generic Defendants to: (a) preclude the entry of less expensive generic versions of Nexium products in the United States; (b) fix, raise, maintain or stabilize the price of Nexium products; (c) permit AstraZeneca to maintain a monopoly in the U.S. market for Nexium products; and (d) allocate 100% of the U.S. market for delayed-release esomeprazole magnesium to AstraZeneca.

90. But for the agreements: (i) Ranbaxy (or another ANDA filer) would have received final marketing approval from the FDA on or about April 14, 2008, and Ranbaxy or another ANDA filer would have begun selling AB-rated versions of Nexium shortly thereafter; and (ii) an increasingly competitive market for delayed-release esomeprazole magnesium would have thereafter emerged as additional generic manufacturers entered the market.

91. Defendants' unlawful concerted action has delayed or prevented the sale of generic Nexium in the United States, and unlawfully enabled AstraZeneca to sell Nexium at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Nexium would have occurred already because one or more of the Generic Defendants would have already entered with its generic version of Nexium.

VII. INTERSTATE COMMERCE

92. At all material times, AstraZeneca manufactured, promoted, distributed, and sold substantial amounts of Nexium in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

93. At all material times, 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 Nexium and/or AB-rated bioequivalents.

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

VIII. MONOPOLY POWER AND MARKET DEFINITION

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

96. A small but significant, non-transitory price increase for Nexium by AstraZeneca would not have caused a significant loss of sales.

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

98. Because of, among other reasons, its use and varying ability to heal erosive esophagitis, maintain the healing of erosive esophagitis, and treat symptomatic gastroesophageal reflux disease, Nexium is differentiated from all products other than AB-rated generic versions of Nexium.

99. AstraZeneca needed to control only Nexium and its AB-rated generic equivalents,

and no other products, in order to maintain the price of Nexium profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Nexium would render AstraZeneca unable to profitably maintain its current prices of Nexium without losing substantial sales.

100. AstraZeneca also sold Nexium at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

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

102. AstraZeneca, 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.

103. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is delayed-release esomeprazole magnesium (*i.e.*, Nexium and its AB-rated generic equivalents). During the period relevant to this case, AstraZeneca has been able to profitably maintain the price of delayed-release esomeprazole magnesium well above competitive levels.

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

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

IX. EFFECTS ON COMPETITION, AND THE DAMAGES CLAIMED IN THIS ACTION

106. Ranbaxy's ANDA was in approvable condition as of February 5, 2008 when it received tentative approval. FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for a 30-month stay. Were it not for the

AstraZeneca/Ranbaxy Agreement, Ranbaxy would have received final FDA approval on or about April 14, 2008, the date the 30-month stay of FDA approval expired. Generic Nexium products would have entered the market shortly thereafter.

107. FDA has not given Ranbaxy's Nexium ANDA final approval solely because FDA knows that the AstraZeneca/Ranbaxy Exclusion Payment Agreement prevents Ranbaxy from selling generic Nexium until May 27, 2014. By practice, FDA organizes its priorities around "rate limiters," and the AstraZeneca/Ranbaxy Agreement is a rate limiter that has caused FDA to wait to issue formal, written approval to Ranbaxy's ANDA. Defendants' Exclusion Payment Agreements had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Nexium from generic competition. Defendants' actions allowed AstraZeneca to maintain a monopoly and to exclude competition in the market for delayed-release esomeprazole magnesium, to the detriment of Plaintiff and all other members of the Class.

108. Defendants' Exclusion Payment Agreements have delayed generic competition and unlawfully enabled AstraZeneca to sell Nexium without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Nexium by April 14, 2008 or shortly thereafter.

109. The generic manufacturers seeking to sell generic Nexium 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.

110. Defendants' Exclusion Payment Agreements, which delayed introduction into the United States marketplace of generic versions of Nexium, have caused Plaintiff and the Class to

pay more than they would have paid for delayed-release esomeprazole magnesium absent Defendants' illegal conduct.

111. 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.

112. 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.

113. But for the Exclusion Payment Agreements, direct purchasers, such as Plaintiff and members of the Class, would have paid less for delayed-release esomeprazole magnesium by (a) substituting purchases of less-expensive AB-rated generic Nexium for their purchases of more-expensive branded Nexium, (b) receiving discounts on their remaining branded Nexium purchases, and (c) purchasing generic Nexium at lower prices sooner.

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

115. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

116. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Nexium directly from AstraZeneca. As a result of Defendants' illegal Exclusion Payment Agreements as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their delayed-release esomeprazole magnesium requirements. Plaintiff and the other Class members paid prices for delayed-release esomeprazole magnesium 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 Nexium instead of expensive brand-name Nexium; (2) Class members paid artificially inflated prices for delayed-release esomeprazole magnesium.

117. As a consequence, Plaintiff 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.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE)
(Asserted against AstraZeneca and Ranbaxy)

118. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

119. At all relevant times, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

120. Through the Exclusion Payment Agreement with Ranbaxy, AstraZeneca and Ranbaxy conspired to maintain AstraZeneca's monopoly power in the relevant market in order to block and delay market entry of delayed-release esomeprazole magnesium, *i.e.*, AB-rated generic versions of Nexium. The unlawful Exclusion Payment Agreement between AstraZeneca and

Ranbaxy allocated all sales of delayed-release esomeprazole magnesium in the United States to AstraZeneca; delayed the sales of generic Nexium products; and fixed the price at which Plaintiff and members of the Class would pay for delayed-release esomeprazole magnesium at the higher, branded price.

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

122. AstraZeneca and Ranbaxy knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market.

123. AstraZeneca and Ranbaxy specifically intended that their Exclusion Payment Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

124. AstraZeneca and Ranbaxy each committed at least one overt act in furtherance of the conspiracy.

125. As a direct and proximate result of Defendants' concerted conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM II: VIOLATION OF 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE)
(Asserted against AstraZeneca and Teva)

126. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

127. At all relevant times, AstraZeneca possessed substantial market power (*i.e.*,

monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

128. Through the Exclusion Payment Agreement with Teva, AstraZeneca and Teva conspired to maintain AstraZeneca's monopoly power in the relevant market in order to block and delay entry of delayed-release esomeprazole magnesium, *i.e.*, AB-rated generic versions of Nexium. The unlawful Exclusion Payment Agreement between AstraZeneca and Teva allocated all sales of delayed-release esomeprazole magnesium in the United States to AstraZeneca; delayed the sales of generic Nexium products; and fixed the price at which Plaintiff and members of the Class would pay for delayed-release esomeprazole magnesium at the higher, branded price.

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

130. AstraZeneca and Teva knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market.

131. AstraZeneca and Teva specifically intended that their Exclusion Payment Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

132. AstraZeneca and Teva each committed at least one overt act in furtherance of the conspiracy.

133. As a direct and proximate result of Defendants' concerted conduct, as alleged

herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM III: VIOLATION OF 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE)
(Asserted against AstraZeneca and Dr. Reddy's)

134. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

135. At all relevant times, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

136. Through the Exclusion Payment Agreement with Dr. Reddy's, AstraZeneca and Dr. Reddy's conspired to maintain AstraZeneca's monopoly power in the relevant market in order to block and delay entry of delayed-release esomeprazole magnesium, *i.e.*, AB-rated generic versions of Nexium. The unlawful Exclusion Payment Agreement between AstraZeneca and Dr. Reddy's allocated all sales of delayed-release esomeprazole magnesium in the United States to AstraZeneca; delayed the sales of generic Nexium products; and fixed the price at which Plaintiff and members of the Class would pay for delayed-release esomeprazole magnesium at the higher, branded price.

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

138. AstraZeneca and Dr. Reddy's knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market.

139. AstraZeneca and Dr. Reddy's specifically intended that their Exclusion Payment Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

140. AstraZeneca and Dr. Reddy's each committed at least one overt act in furtherance of the conspiracy.

141. As a direct and proximate result of Defendants' concerted conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM IV: VIOLATION OF 15 U.S.C. § 1
(AGREEMENT RESTRAINING TRADE)
(Asserted against AstraZeneca and Ranbaxy)

142. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

143. In or about April 2008 and at times prior to the formal execution thereof AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Ranbaxy substantial consideration in exchange for Ranbaxy's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

144. The Agreement harmed Plaintiff and the Class as set forth above.

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

146. AstraZeneca and Ranbaxy are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

147. 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.

148. As a direct and proximate result of AstraZeneca's and Ranbaxy's anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM V: VIOLATION OF 15 U.S.C. § 1
(AGREEMENT RESTRAINING TRADE)
(Asserted against AstraZeneca and Teva)

149. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

150. In or about January 2010, and at times prior to the formal execution thereof AstraZeneca and Teva entered into the AstraZeneca/Teva Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Teva substantial consideration in exchange for Teva's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 4 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

151. The Agreement harmed Plaintiff and the Class as set forth above.

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

153. AstraZeneca and Teva are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

154. 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.

155. As a direct and proximate result of AstraZeneca's and Teva's anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM VI: VIOLATION OF 15 U.S.C. § 1
(AGREEMENT RESTRAINING TRADE)
(Asserted against AstraZeneca and Dr. Reddy's)

156. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

157. Beginning in January 2011, and at times prior to the formal execution thereof AstraZeneca and Dr. Reddy's entered into the AstraZeneca/Teva Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Dr. Reddy's substantial consideration in exchange for Dr. Reddy's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 3 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

158. The Agreement harmed Plaintiff and the Class as set forth above.

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

160. AstraZeneca and Dr. Reddy's are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

161. 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.

162. As a direct and proximate result of AstraZeneca's and Dr. Reddy's' anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, 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 the Plaintiff as the representative of the Class;

B. Enter joint and several judgments against Defendants and in favor of Plaintiff 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 Plaintiff and the Class their costs of suit, including reasonable attorneys' fees

as provided by law.

XII. JURY DEMAND

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

Dated: August 29, 2012

Respectfully submitted,

PROFESSIONAL DRUG COMPANY, INC.

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