

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MICHIGAN REGIONAL COUNCIL
OF CARPENTERS EMPLOYEE
BENEFITS FUND, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

ASTRAZENECA
PHARMACEUTICALS LP,
AKTIEBOLAGET HASSLE,
ASTRAZENECA AB, 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.,

Defendants.

Civil Action No.:

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Michigan Regional Council of Carpenters Employee Benefits Fund (“Plaintiff” or “the Fund”), on behalf of itself and all others similarly situated, files this class action complaint (the “Complaint”) against Defendants AstraZeneca Pharmaceuticals LP, Aktiebolaget Hassle, AstraZeneca AB (collectively, “AstraZeneca”); Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc. and Ranbaxy

Laboratories Ltd. (collectively, “Ranbaxy”); Teva Pharmaceutical Industries, Ltd. and Teva USA, Inc. (collectively, “Teva”); Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “Dr. Reddy’s”) (together, the “Generic Defendants,” and together with AstraZeneca, the “Defendants”); based upon personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, alleges as follows:

I. NATURE OF THE ACTION

1. This action arises out of Defendants’ conspiracy to allocate and unreasonably restrain trade in the market for 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 of 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 generic versions of Nexium. But for the Agreements, generic versions of Nexium would have been available to Plaintiff and members of the Class in the United States as early as April 14, 2008, when the 30-month stay of the U.S. Food and Drug Administration’s (the “FDA”) approval of Ranbaxy’s generic version of Nexium expired.

3. Generic versions of brand-name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. The only material difference between generic and

brand-name drugs is their price: generics are usually at least 25% less expensive than their brand-name counterparts when there is a single generic competitor. This discount typically increases to 50%-80%, or more, when there are multiple generic competitors on the market for a brand-name product. 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. The U.S. Federal Trade Commission estimates that about one year after market entry, the generic competitor takes over 90% of the brand-name drug's unit sales, and sells for 15% of the price.

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 on the chance 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 (frequently called "Exclusion Payments" or "Reverse Payments") as payments to compensate them for: (1) supplying a portion of AstraZeneca's 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 (2) 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 esomeprazole magnesium products. In light of the substantial possibility that AstraZeneca's Nexium patents would be invalidated and/or that the Generics Defendants' 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 Nexium sales - 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 esomeprazole magnesium market until May 27, 2014.

7. Like AstraZeneca, the Generic Defendants knew 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 versions of Nexium. Once there are multiple generic versions of a brand-name 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-name drug 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. That is precisely what happened.

8. AstraZeneca and Ranbaxy also knew, and intended, that their Exclusion Payment Agreement would prevent other generic competitors from launching their own generic version of Nexium before Ranbaxy did, thereby creating a "bottleneck." As the first filer of an Abbreviated New Drug Application

(“ANDA”) for a generic version of Nexium, Ranbaxy is entitled to market its generic product for 180 days free from competition from other generic versions of Nexium products. The operation of the Exclusion Payment Agreement between AstraZeneca and Ranbaxy can block any other generic versions of Nexium products from coming to market until 180 days after May 27, 2014, because, absent circumstances discussed below, the FDA will not approve subsequently filed ANDAs until the first-filer’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 versions of Nexium within 75 days of a court decision that all of the patents listed in the FDA’s book, *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 Payments 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 esomeprazole magnesium products expired. The FDA had granted tentative approval to Ranbaxy’s generic version of Nexium product 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 not to compete, Plaintiff and the members of the Class would have already been able to purchase, and would have purchased, generic esomeprazole magnesium at significantly lower prices, rather than being forced to pay high prices for Nexium.

11. Defendants' unlawful Exclusion Payment Agreements were designed to and did in fact: (1) preclude the entry of less expensive generic esomeprazole magnesium products in the United States; (2) fix, raise, maintain, or stabilize the price of esomeprazole magnesium products; (3) permit AstraZeneca to maintain a monopoly in the United States for esomeprazole magnesium; and (4) allocate 100% of the U.S. esomeprazole magnesium market to AstraZeneca.

12. This action is brought as a class action on behalf of all consumers and third-party payors in the United States who purchased or paid for brand-name and/or generic versions of Nexium products, other than for resale, since April 14, 2008 (*see* Class definitions below). Plaintiff seeks a judgment declaring that Defendants' Exclusion Payment Agreements, as further described below, are unlawful under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, enjoining the continuation of the anti-competitive Agreements. Unless enjoined, Defendants' unlawful conduct will continue unchecked, and Plaintiff and the End-Payor Classes will continue to bear the financial brunt of Defendants' antitrust violations.

13. This action is also brought as a class action on behalf of all consumers and third-party payors in the states of: Alabama, Arizona, California, Florida, Georgia, Illinois, Nevada, New York, North Carolina, North Dakota, Michigan, Minnesota, Mississippi, Tennessee, Utah, and Wisconsin, who purchased or paid for brand-name and/or generic versions of Nexium products, other than for resale, since April 14, 2008 (*see* Class definitions below). Plaintiff seeks compensatory

and/or treble damages and equitable relief for continuing violations of the below-referenced state antitrust and consumer protection laws, and for unjust enrichment and disgorgement under those states' common law.

II. PARTIES

A. Plaintiff

14. Michigan Regional Council of Carpenters Employee Benefits Fund is a Taft-Hartley fund located in Troy, Michigan that provides health and welfare benefits to its union membership. The Fund is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor-Management Relations Act ("LMRA"), 29 U.S.C. §186(c)(5). As such, the Fund is entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Beneficiaries of Plaintiff purchased brand-name and/or generic versions of Nexium products during the Class Period for personal use. Plaintiff is ultimately at risk and responsible for reimbursing or paying for members' purchases of prescription drugs, such as Nexium. Plaintiff and its beneficiaries have been injured in their business or property by having paid or reimbursed more for brand-name and/or generic versions of Nexium products than they would have absent the Defendants' illegal and anticompetitive conduct alleged herein. Plaintiff was injured by the illegal, anticompetitive, and unjust and deceptive conduct described herein, both individually and in a manner that was common and typical of End-Payor Class members.

B. Defendants

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

16. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business in Södertälje, Sweden.

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

18. 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 32257, and having its place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540. Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

19. 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.

20. Defendant Ranbaxy Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

21. Defendants Ranbaxy Pharmaceuticals Inc., Ranbaxy Laboratories Limited, and Ranbaxy Inc. are engaged in the worldwide marketing, production, and distribution of generic pharmaceutical products.

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

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

24. Defendants Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. are the largest generic manufacturer of pharmaceuticals in the world.

25. 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.

26. Defendant Dr. Reddy's Laboratories Inc. is a New Jersey corporation with its principal place of business at 200 Somerset Corp. Blvd. #7, Bridgewater, New Jersey 08807. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd.

27. 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.

III. JURISDICTION AND VENUE

28. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

29. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. §26 and 28 U.S.C. §§1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. §26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act,

15 U.S. C. §§1 and 2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. §1367.

30. Venue is 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), because two of the Defendants are located and transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

IV. REGULATORY BACKGROUND

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

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug product must obtain the FDA approval to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§301-92. 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).

32. When the FDA approves a brand-name manufacturer's NDA, the manufacturer may list in the Orange Book any patents it 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 its listed patents. Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§355(b)(1) and (c)(2).

33. 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

34. 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 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-name drug — that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand-name drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an “AB” rating.

35. 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, 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 brand-name counterpart. 21 U.S.C. §355(j)(8)(B).

36. 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.

37. 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 brand-name 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

38. 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:

- i. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");
- ii. that the patent for the brand-name drug has expired (a "Paragraph II certification");
- iii. that the patent for the brand-name drug will expire on a particular date, and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

39. 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 45 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

(1) the passage of 30 months, or (2) 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. The 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.

40. As an incentive to spur generic companies to seek approval of generic alternatives to brand-name 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 competitors. 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 product is the only available generic for at least six months.

41. 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 30 months. That brand-name manufacturers often sue generic competitors 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.

42. The first generic applicant can help the brand-name 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 to delay marketing of 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 competitor applicants cannot launch until the first generic competitor applicant’s 180-day exclusivity has elapsed or is forfeited.

3. Forfeiture Provisions Under the MMA

43. 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-name and generic pharmaceutical companies to conspire in order 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 generic products.

44. 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’s Orange Book.

45. Brand-name manufacturers and first-filing generic competitors 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 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-name company did not assert against it in a Paragraph IV Litigation.

B. The Benefits of Generic Drugs

46. Typically, AB-rated generics cost much less than their brand-name 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. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand-name prescriptions (unless the prescribing physician has specifically ordered otherwise by writing on the prescription “dispense as written”).

47. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic products. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic equivalents for more expensive brand-name products. Health insurers are contractually obligated to pay for the bulk of

their members' prescriptions, whether filled with brand-name or generic drugs, so they offer their members lower co-pays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if brand-name prescription drug costs continue to rise.

48. As more generic equivalents compete with each other, prices decline even further as a result 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. The speed with which generic drugs take over the market is increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics held, on average, a 44% market share after one year; by 2008, generic versions could capture as much as 86%-97% of the market within the first month of availability. 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.

49. However, until a generic version of the brand-name drug enters the market, there is no bioequivalent generic drug to substitute for and 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. As a result, brand-name drug manufacturers, who are well aware of generics' rapid erosion of their brand-name drug sales, have a strong incentive to delay the introduction of generic competition into the market, including using tactics such as the Agreements alleged above and below.

V. FACTUAL ALLEGATIONS

A. Defendants' Unlawful Conduct

1. AstraZeneca Files Paragraph IV Litigation Against the Generic Defendants

50. 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, or reasonably interchangeable with, Nexium.

51. On December 3, 1999, AstraZeneca submitted NDA 21-153, seeking FDA approval to market 20 mg and 40 mg strengths of esomeprazole magnesium in delayed-release capsules 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.

52. In connection with its Nexium NDA, AstraZeneca listed at least 13 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.

53. 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.

54. 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 and right hands 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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 esomeprazole magnesium product would not infringe any valid claim of any patent expiring after October 2007 listed in the FDA’s Orange Book as covering Nexium or a method of using Nexium.

60. On November 21, 2005, AstraZeneca filed suit in the U.S. District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Ranbaxy’s generic esomeprazole magnesium 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”).

61. 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 products would not infringe any valid claim of any patent listed in the FDA's Orange Book as covering Nexium or a method of using Nexium.

62. On March 8, 2006, AstraZeneca filed suit against Teva in the U.S. District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Teva's generic esomeprazole magnesium products 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").

63. 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 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 products would not infringe the '504, '192, or '872 patents, and/or that those patents were invalid.

64. On January 17, 2008, AstraZeneca filed suit in the U.S. District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Dr. Reddy's generic esomeprazole magnesium 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 products would infringe the '192 patent.

65. 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 Exclusion Payment Agreements before any dispositive motions relating to the Generic Defendants' substantive challenges to the patents were decided.

66. To prevent generic entry using just its patents (rather than pay-offs), AstraZeneca would have had to show that each of the generic esomeprazole magnesium products infringed its patents and defeat each of the Generic Defendants' 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 versions of Nexium. And that is precisely what it has done, in concert with the Generic Defendants.

2. AstraZeneca and Ranbaxy Enter an Exclusion Payment Agreement

67. 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 by the court on the exact day that the 30-month stay of FDA approval of Ranbaxy's generic esomeprazole magnesium product expired.

68. Under the Exclusion Payment Agreement, Ranbaxy agreed to: (1) admit that the '504, '192, '789, '085, '810, and '872 patents were enforceable and valid; (2) admit that its generic esomeprazole magnesium products would infringe the '504, '192, '789, and '872 patents, but not the '810 or '085 patents; and (3)

delay launching its generic product until May 27, 2014, unless otherwise specifically authorized by the Agreement.

69. 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 esomeprazole magnesium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Ranbaxy hundreds of millions of dollars. Shortly after AstraZeneca and Ranbaxy entered the Agreement, Ranbaxy's former 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.

70. 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 six years. Absent Ranbaxy's agreement to delay entry into the market with generic versions of 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 other terms that it did under those provisions of the Agreement. AstraZeneca paid Ranbaxy for the delayed market entry of generic esomeprazole magnesium.

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

71. On April 30, 2008, shortly after AstraZeneca and Ranbaxy entered into 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 version of Nexium ANDA. *IVAX Pharma v. AstraZeneca*, No. 3:08-cv-02165-JAP (D.N.J.) (IVAX was acquired by Teva Pharmaceuticals Industries in January 2006 and operates as part of the corporation's Active Pharmaceutical Ingredients Division.). 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.

72. 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***." *IVAX Pharma v. AstraZeneca*, No. 3:08-cv-02165-JAP, Plaintiff's Brief in Opposition to Defendant's Motion Under Fed. R. Civ. P. 12(b)(1) to Dismiss for Lack of Subject Matter Jurisdiction at 7 (D.N.J. Aug. 5, 2008). According to Teva, as a result of the AstraZeneca/Ranbaxy Exclusion Payment Agreement, 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.*" *Id.*

73. The court denied, in substantial part, AstraZeneca's motion to dismiss the declaratory judgment actions, but granted AstraZeneca's motion to stay the declaratory action pending resolution of the main infringement action. Although, on reconsideration, the court permitted the declaratory judgment actions to proceed, AstraZeneca succeeded in delaying for 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

74. In the interim, however, Teva and AstraZeneca entered into an Exclusion Agreement. Although claim construction was briefed during summer 2009, AstraZeneca and Teva, pursuant to their 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.

75. Under the Exclusion Payment Agreement, Teva agreed to: (1) admit that all patents then listed in the Orange Book as covering Nexium "are all enforceable and valid with respect to certain products"; (2) admit that its generic esomeprazole magnesium product would infringe the '504, '192, '789, '085, '872, and '070 patents; and (3) delay launching its generic product until May 27, 2014, unless otherwise specifically authorized by the Agreement.

76. As the *quid pro quo* for Teva's agreement to drop its challenge to the Nexium Patents, and to delay entry of its generic esomeprazole magnesium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Teva. That payment came in the form of AstraZeneca's forgiveness of Teva from a contingent liability.

77. Teva had an enormous contingent liability to AstraZeneca. On September 9, 2004, Teva had commenced an "at risk" launch of generic version of Prilosec, which was manufactured by its marketing partner, Impax. In 2008, the Federal Circuit affirmed a district court's ruling that the Prilosec patents were valid and infringed by Impax's generic version of Prilosec product. Because Teva and Impax shared the risk with respect to any damages associated with the sale of the generic version of Prilosec products, there was substantial risk that Teva would owe AstraZeneca potentially massive infringement damages resulting from years of infringing Prilosec sales. As part of, and simultaneously with, 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 its 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.

78. The true purpose and effect of AstraZeneca's 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 its generic esomeprazole magnesium product, 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 the delayed market entry of its generic esomeprazole magnesium product.

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

79. 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 into 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 esomeprazole magnesium products until May 27, 2014, unless specifically authorized by the Agreement. Dr. Reddy's made no admissions regarding validity or infringement.

80. 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.

81. 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 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.

82. The true purpose and effect of AstraZeneca's 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 esomeprazole magnesium, 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 the delayed market entry of its generic esomeprazole magnesium product.

83. By paying Teva and Dr. Reddy's not to market their generic esomeprazole magnesium 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

84. AstraZeneca's payments to the Generic Defendants under the Exclusion Payment Agreements demonstrate Defendants' anticompetitive purpose and intent.

85. The Agreements harmed Plaintiff and the End-Payor Classes by depriving them of a market in which generic drug manufacturers and distributors make decisions about challenging patents, defending appeals, and entering markets free from the influence of cash payments and other consideration. Contrary to the purpose of the Hatch-Waxman Act, the Agreements have enabled AstraZeneca and the Generic Defendants to: (1) preclude the entry of less expensive generic versions of Nexium products in the United States; (2) fix, raise, maintain, or stabilize the price of Nexium products; (3) permit AstraZeneca to maintain a monopoly in the U.S. market for Nexium products; and (4) allocate 100% of the U.S. market for esomeprazole magnesium to AstraZeneca.

86. But for the Agreements: (1) 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 generic versions of Nexium shortly thereafter; and (2) an increasingly competitive market for esomeprazole magnesium would have emerged following the expiration of Ranbaxy's 180-day exclusivity period as additional generic manufacturers entered the market.

87. Defendants' unlawful concerted action has delayed or prevented the sale of generic versions of 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 the market with its generic version of Nexium.

VI. CLASS ACTION ALLEGATIONS

88. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(2), for declaratory and injunctive relief, as representatives of a U.S. End-Payor Class defined as follows:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Nexium and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "U.S. End-Payor Class"), other than for resale, during the period April 14, 2008 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Nexium or its generic equivalent if they paid or reimbursed some or all of the purchase price.

89. Plaintiff brings this action on behalf of itself, and pursuant to Fed. R. Civ. P. 23(a) and (b)(3), for money damages, as representatives of the State End-Payor Class defined as follows:

All persons or entities in Alabama, Arizona, California, Florida, Georgia, Illinois, Nevada, New York, North Carolina, North Dakota, Michigan, Minnesota, Mississippi, Tennessee, Utah, and Wisconsin, who, in those states, purchased and/or paid for some or all of the purchase price for Nexium and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "State End-Payor Class"), other than for resale, during the period April 14, 2008, through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class

definition, persons or entities “purchased” Nexium or its generic equivalent if they paid or reimbursed some or all of the purchase price.

90. The following persons or entities are excluded from the proposed U.S. End-Payor and State End-Payor Classes (collectively, “End-Payor Classes”):

- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. All governmental entities, except for governmental-funded employee benefit plans;
- c. All persons or entities who purchased Nexium or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan’s reimbursement obligations to its members);
- e. Any “flat co-pay” consumers whose purchases were paid in part by a third-party payor, and whose co-payment was the same regardless of the retail purchase price;
- f. Any “brand loyalist” consumers or third-party payors who purchased Nexium, and who did not purchase any AB-rated generic equivalent after such generics became available; and
- g. The judges in this case and any members of their immediate families.

91. Members of the End-Payor Classes are so numerous that joinder is impracticable. Plaintiff believes that the End-Payor Classes includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

92. Plaintiff’s claims are typical of the claims of the members of the End-Payor Classes. Plaintiff and all members of the End-Payor Classes were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Nexium and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Nexium as a result of Defendants’ wrongful conduct.

93. Plaintiff will fairly and adequately protect and represent the interests of the End-Payor Classes. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the End-Payor Classes.

94. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

95. Questions of law and fact common to the members of the End-Payor Classes predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire End-Payor Classes, thereby making overcharge damages with respect to the End-Payor Classes as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

96. Questions of law and fact common to the End-Payor Classes include, but are not limited to:

- a. whether Defendants conspired to willfully maintain and/or enhance AstraZeneca's monopoly power over Nexium and its generic equivalents;
- b. whether Defendants conspired to suppress generic competition to Nexium;
- c. whether Defendants entered into an unlawful agreement in restraint of trade;
- d. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic versions of Nexium;
- e. whether, pursuant to the Agreements, AstraZeneca compensated the Generic Defendants;
- f. whether AstraZeneca's compensation to the Generic Defendants was for a purpose other than delayed entry of generic versions of Nexium;
- g. whether AstraZeneca's compensation to the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and non- pretextual;

- h. whether the Agreements created a bottleneck to generic competition;
- i. whether AstraZeneca possessed monopoly power over Nexium;
- j. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;
- k. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- l. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the End-Payor Classes;
- m. whether, and to what extent, Defendants' misconduct constitutes misleading and deceptive conduct, unconscionable conduct, and/or unfair and deceptive acts and practices;
- n. whether Defendants have been unjustly enriched by virtue of their misconduct to the detriment of members of the End-Payor Classes; and
- o. the amount of damage suffered by the End-Payor Classes and/or the extent to which Defendants have been unjustly enriched by virtue of their misconduct.

97. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. 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, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

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

VII. INTERSTATE COMMERCE

99. 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.

100. 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.

101. In furtherance of their efforts to monopolize and restrain competition in the market for esomeprazole magnesium, Defendants employed the U.S. 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 RELEVANT MARKET

102. At all relevant times, AstraZeneca had monopoly power over 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.

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

104. 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.

105. 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.

106. 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.

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

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

109. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

110. 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 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 esomeprazole magnesium well above competitive levels.

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

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

IX. ANTI-COMPETITIVE EFFECTS

113. Ranbaxy's ANDA was in approvable condition as of February 5, 2008, when it received tentative approval. The FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval, but

for the 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 esomeprazole magnesium products would have entered the market shortly thereafter.

114. The FDA has not given Ranbaxy's generic esomeprazole magnesium ANDA final approval solely because the FDA knows that the AstraZeneca/Ranbaxy Exclusion Payment Agreement prevents Ranbaxy from selling its generic product until May 27, 2014. By practice, the FDA organizes its priorities around "rate limiters," and the AstraZeneca/Ranbaxy Agreement is a rate limiter that has caused the FDA to wait to issue formal, written approval to Ranbaxy's ANDA.

115. 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 esomeprazole magnesium, to the detriment of Plaintiff and all other members of the End-Payor Classes.

116. 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.

117. The generic manufacturers seeking to sell generic esomeprazole magnesium 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.

118. Defendants' Exclusion Payment Agreements, which delayed introduction into the U.S. marketplace of generic versions of Nexium, have caused Plaintiff and members of the End-Payor Classes to pay more than they would have paid for esomeprazole magnesium absent Defendants' illegal conduct.

119. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding brand-name drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand-name drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drugs to: (a) purchase generic versions of a drug at substantially lower prices, 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.

120. But for the Exclusion Payment Agreements, consumers, such as Plaintiff and members of the End-Payor Classes, would have paid less for esomeprazole magnesium by: (1) substituting purchases of less expensive AB-rated generic versions of Nexium for their purchases of more expensive brand-name Nexium; (2) receiving discounts on their remaining Nexium purchases; and (3) purchasing generic products at lower prices sooner.

121. 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.

122. During the Class Period, Plaintiff and other members of the End-Payor Classes purchased substantial amounts of Nexium. As a result of Defendants' illegal conduct as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for generic versions of Nexium. Plaintiff and members of the End-Payor Classes paid prices for esomeprazole magnesium that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) members of the End-Payor Classes were deprived of the opportunity to purchase lower-priced generic versions of Nexium instead of the more expensive brand-name Nexium; and (2) members of the End-Payor Classes paid artificially inflated prices for esomeprazole magnesium.

123. As a consequence, Plaintiff and members of the End-Payor Classes 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.

124. Thus, Defendants' unlawful conduct deprived Plaintiff and members of the End-Payor Classes of the benefits of competition that the antitrust laws were designed to ensure.

X. CLAIMS FOR RELIEF

COUNT I

(Contract, Combination, or Conspiracy in Restraint of Trade in Violation of Section 1 of the Sherman Act, 15 U.S.C. §1)

125. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

126. The Exclusion Payment Agreements between AstraZeneca and each of the Generic Defendants involve: (1) a payment from AstraZeneca to the respective Generic Defendant, and (2) an agreement by the Generic Defendant to

delay marketing its generic esomeprazole magnesium product until May 27, 2014. The payments from AstraZeneca to the Generic Defendants under the Agreements were the *quid pro quo* for the Generic Defendants' agreement to delay marketing of their generic versions of Nexium for as long as six years or more. Absent the payments, the Generic Defendants would not have agreed to delay marketing their generic products until May 27, 2014.

127. The purpose and effect of the unlawful Exclusion Payment Agreements between AstraZeneca and each of the Generic Defendants was to allocate 100% of the esomeprazole magnesium market in the United States to AstraZeneca; delay the sales of generic esomeprazole magnesium products for six years or more; and fix the price at which consumers and other End-Payor Plaintiffs would pay for esomeprazole magnesium at the higher, brand-name price.

128. Each of the Exclusion Payment Agreements constitutes a continuing contract, combination, and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Each of the Exclusion Payment Agreements is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the *per se* "quick look" or rule of reason standard. The purpose and effect of the payments flowing from AstraZeneca to the Generic Defendants under the Agreements was to delay generic competition to Nexium, and there is, and was, no legitimate, nonpretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

129. Each of the Exclusion Payment Agreements harmed competition in the relevant market.

130. AstraZeneca's anti-competitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have

been able to charge absent its unlawful actions, individually and with Generic Defendants.

131. The prices were inflated as a direct and foreseeable result of AstraZeneca's anticompetitive conduct, individually and with Generic Defendants.

132. The inflated prices the U.S. End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and the Generic Defendants.

133. During the relevant period, Plaintiff and members of the U.S. End-Payor Classes purchased substantial amounts of Nexium indirectly from Defendants and/or purchased substantial amounts of AB-rated generic esomeprazole magnesium products indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the U.S. End-Payor Classes were compelled to pay, and did pay, artificially inflated prices for esomeprazole magnesium. Those prices were substantially greater than the prices that members of the U.S. End-Payor Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Nexium was artificially inflated by Defendants' illegal conduct; (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Nexium; and/or (3) the price of AB-rated generic esomeprazole magnesium was artificially inflated by Defendants' illegal conduct.

134. As a consequence, Plaintiff and members of the U.S. End-Payor Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

135. Plaintiff and the U.S. End-Payor Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. §2201(a), hereby seek a declaratory judgment that Defendants' conduct as described herein violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2.

136. Plaintiff and the U.S. End-Payor Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

COUNT II
(Monopolization in Violation of Section 2 of the Sherman Act, 15 U.S.C. §2)

137. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

138. 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.

139. Through the Exclusion Payment Agreements, Defendants knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market and to exclude the Generic Defendants' generic version of Nexium from the market for as long as six years or more.

140. AstraZeneca and the Generic Defendants specifically intended that the Exclusion Payment Agreements would maintain AstraZeneca's monopoly power in the relevant market, and thereby injured Plaintiff and the U.S. End-Payor Class.

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

142. As a direct and proximate result of Defendants' unlawful maintenance and conspiracy to maintain AstraZeneca's monopoly power, Plaintiff and members of the U.S. End-Payor Class were harmed as described herein.

143. AstraZeneca's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions, individually and with Generic Defendants.

144. The prices were inflated as a direct and foreseeable result of AstraZeneca's anticompetitive conduct, individually and with Generic Defendants.

145. The inflated prices the U.S. End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and the Generic Defendants.

146. During the Class Period, Plaintiff and members of the U.S. End-Payor Class purchased substantial amounts of Nexium indirectly from Defendants and/or purchased substantial amounts of AB-rated generic esomeprazole magnesium products indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the U.S. End-Payor Class were compelled to pay, and did pay, artificially inflated prices for esomeprazole magnesium. Those prices were substantially greater than the prices that members of the U.S. End-Payor Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Nexium was artificially inflated by Defendants' illegal conduct; (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Nexium; and/or (3) the price of generic esomeprazole magnesium was artificially inflated by Defendants' illegal conduct.

147. As a consequence, Plaintiff and members of the U.S. End-Payor Class have sustained substantial losses and damage to their business and property in the

form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

148. Plaintiff and the U.S. End-Payor Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. §2201(a), hereby seek a declaratory judgment that Defendants' conduct as described herein violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2.

149. Plaintiff and the U.S. End-Payor Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

COUNT III
**(Contract, Combination, or Conspiracy in Restraint of
Trade in Violation of State Law)**

150. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

151. The Exclusion Payment Agreements between AstraZeneca and each of the Generic Defendants involve: (1) a payment from AstraZeneca to the respective Generic Defendant, and (2) an agreement by the Generic Defendant to delay marketing of its generic version of Nexium until May 27, 2014. The payments from AstraZeneca to the Generic Defendants under the Agreements were the *quid pro quo* for the Generic Defendants' agreement to delay marketing of their generic versions of Nexium for as long as six years or more. Absent the payments, the Generic Defendants would not have agreed to delay marketing their generic versions of Nexium until May 27, 2014.

152. The purpose and effect of the unlawful Exclusion Payment Agreements between AstraZeneca and each of the Generic Defendants was to allocate 100% of the esomeprazole magnesium market in the United States to

AstraZeneca; delay the sales of their generic products for up to six years or more; and fix the price at which consumers and other End-Payor Plaintiffs would pay for esomeprazole magnesium at the higher, brand-name price.

153. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a contract, combination, and conspiracy to restraint trade in violation of Alabama Code §8-10-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Alabama by members of the State End-Payor Class;
- b. Defendants have intentionally and wrongfully engaged in a contract, combination, and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §44-1401, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Arizona by members of the State End-Payor Class;
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of California Bus. & Prof. Code §16700, *et seq.*, and §17200, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in California by members of the Class;
- d. Defendants have intentionally and wrongfully engaged in a contract, combination, and conspiracy in restraint of trade in violation of Florida Stat. §501, Part II, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act;

- e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Michigan Comp. Laws Ann. §445.771, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Michigan by members of the Class;
- f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minnesota Stat. §325D.52, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Minnesota by members of the Class;
- g. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mississippi Code Ann. §75-21-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Mississippi by members of the Class;
- h. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nevada Rev. Stat. Ann. §598A, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Nevada by members of the Class, in that thousands of sales of Nexium took place at Nevada pharmacies, and purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;
- i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York Gen. Bus. Law §340, *et seq.*, with respect to

purchases of Nexium and AB-rated generic equivalents in New York by members of the Class;

- j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of North Carolina Gen. Stat. §75-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in North Carolina by members of the Class;
- k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of North Dakota Code §51-08.1-01, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in North Dakota by members of the Class;
- l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tennessee Code Ann. §47-25-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Nexium and AB-rated generic equivalents at Tennessee pharmacies;
- m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §76-10-911, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Utah by members of the Class; and

- n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wisconsin Stat. §133.01, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Nexium at Wisconsin pharmacies.

154. Plaintiff and members of the State End-Payor Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic esomeprazole magnesium products; and (2) paying higher prices for esomeprazole magnesium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above states were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

155. Plaintiff and the State End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT IV
(Monopolization in Violation of State Law)

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

157. 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.

158. Through the Exclusion Payment Agreements, Defendants knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market, and to exclude the Generic Defendants' generic versions of Nexium from the market for as long as six years or more.

159. AstraZeneca and the Generic Defendants specifically intended that the Exclusion Payment Agreements would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

160. The goal, purpose, and/or effect of the Exclusion Payment Agreements were to maintain and extend AstraZeneca's monopoly power in the U.S. market for esomeprazole magnesium.

161. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Alabama Code §8-10-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Alabama by members of the State End-Payor Class;
- b. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §44-1401, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Arizona by members of the State End-Payor Class;
- c. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of California Bus. & Prof. Code §16700, *et seq.*, and §17200, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in California by members of the Class;

- d. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Florida Stat. §501, Part II, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act;
- e. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Michigan Comp. Laws Ann. §445.771, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Michigan by members of the Class;
- f. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Minnesota Stat. §325D.52, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Minnesota by members of the Class;
- g. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Mississippi Code Ann. §75-21-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Mississippi by members of the Class;
- h. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Nevada Rev. Stat. Ann. §598A, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Nevada by members of the Class, in that thousands of sales of Nexium took place

at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

- i. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of New York Gen. Bus. Law §340, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New York by members of the Class;
- j. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of North Carolina Gen. Stat. §75-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in North Carolina by members of the Class;
- k. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of North Dakota Cent. Code §51-08.1-01, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in North Dakota by members of the Class;
- l. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Tennessee Code Ann. §47-25-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Nexium and AB-rated generic equivalents at Tennessee pharmacies;
- m. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in

violation of Utah Code Ann. §76-10-911, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Utah by members of the Class; and

- n. Defendants have intentionally and wrongfully engaged in monopolization and a conspiracy to monopolize the relevant market in violation of Wisconsin Stat. §133.01, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Nexium at Wisconsin pharmacies.

162. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain AstraZeneca's monopoly power, Plaintiff and members of the State End-Payor Class paid artificially inflated prices for esomeprazole magnesium as described herein, and were harmed as a result.

163. Plaintiff and members of the State End-Payor Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic esomeprazole magnesium products; and (2) paying higher prices for esomeprazole magnesium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above states were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

164. Plaintiff and the State End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT V
(Unfair and Deceptive Acts and Practices Under State Law)

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

166. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the State End-Payor Class were deprived of the opportunity to purchase a generic version of Nexium, and forced to pay higher prices. By engaging in the foregoing conduct, Defendants have violated the following state Unfair and Deceptive Trade Practices and Consumer Fraud laws:

- a. Defendants have engaged in unfair competition or unfair or deceptive trade practices in violation of Alabama Code. §8-19-1, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Alabama by members of the State End-Payor Class;
- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Arizona by members of the State End-Payor Class;
- c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of California Bus. & Prof. Code §17200, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in California by members of the State End-Payor Class;

- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Stat. §501.201, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Florida by members of the State End-Payor Class;
- e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Illinois Comp. Stat. 815 ILCS §505/1, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Illinois by members of the State End-Payor Class;
- f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Michigan Comp. Laws §445.901, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Michigan by members of the State End-Payor Class;
- g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minnesota Stat. §8.31, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Minnesota by members of the State End-Payor Class;
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nevada Rev. Stat. §598.0903, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Nevada by members of the State End-Payor Class;
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of New York Gen. Bus.

Law §349, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in New York by members of the State End-Payor Class;

- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of North Carolina Gen. Stat. §75-1.1, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in North Carolina by members of the State End-Payor Class;
- k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of North Dakota Cent. Code §51-10-01, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in North Dakota by members of the State End-Payor Class;
- l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tennessee Code Ann. §47-18-101, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Tennessee by members of the State End-Payor Class;
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code §13-11-1, *et seq.*, with respect to purchases of Nexium and AB-rated bioequivalents in Utah by members of the State End-Payor Class; and
- n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wisconsin Stat. §100.18, *et seq.*, with respect to purchases of Nexium and AB-

rated bioequivalents in Wisconsin by members of the State End-Payor Class.

167. Plaintiff and members of the State End-Payor Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Nexium and/or AB-rated bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent, and directly results from Defendants' unlawful conduct.

168. Plaintiff and the State End-Payor Class seek damages and injunctive and declaratory relief as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT VI
(Unjust Enrichment Under State Law)

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

170. Defendants have benefited from splitting the monopoly profits on AstraZeneca's Nexium sales resulting from the unlawful and inequitable acts alleged in this Complaint.

171. Defendants' financial benefits resulting from their unlawful and inequitable conduct are directly traceable to overpayments foresomeprazole magnesium by Plaintiff and members of the State End-Payor Class.

172. Plaintiff and the State End-Payor Class have conferred upon Defendants a direct economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the State End-Payor Class.

173. It would be futile for Plaintiff and the State End-Payor Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and the State End-Payor Class.

174. It would be futile for Plaintiff and the State End-Payor Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Nexium or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

175. In the alternative, Plaintiff and the State End-Payor Class have no adequate remedy at law.

176. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Nexium and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

177. The financial benefits derived by Defendants rightfully belongs to Plaintiff and the State End-Payor Class, as Plaintiff and the State End-Payor Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

178. It would be inequitable under the laws of Alabama, Arizona, California, Florida, Georgia, Illinois, Michigan, Minnesota, Mississippi, Nevada, New York, North Carolina, North Dakota, Tennessee, Utah, and Wisconsin, for the Defendants to be permitted to retain any of the overcharges for Nexium and/or AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

179. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the State End-Payor Class all unlawful or inequitable proceeds received by them.

180. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the State End-Payor Class.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Classes, demands judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the U.S. End-Payor Class, and declare the Plaintiff representative of the U.S. End-Payor Class and the State End-Payor Class;

B. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2, of the state antitrust and consumer protection statutes, and of the common law of unjust enrichment as alleged herein;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiff and the End-Payor Classes;

E. Grant Plaintiff and the State End-Payor Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award Plaintiff and the State End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiff and the End-Payor Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XII. JURY DEMAND

Pursuant to Fed. R. Civ. P. Rule 38, Plaintiff, on behalf of itself and the proposed End-Payor Classes, demands a trial by jury on all issues so triable.

Dated: November 9, 2012

TRUJILLO RODRIGUEZ &
RICHARDS, LLC

s/ Lisa J. Rodriguez
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Counsel for Plaintiff

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

MICHIGAN REGIONAL COUNCIL OF CARPENTERS EMPLOYEE BENEFITS FUND

(b) County of Residence of First Listed Plaintiff Oakland County, MI
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, Telephone Number, and Email Address)
Lisa J. Rodriguez, Trujillo Rodriguez & Richards, LLC
258 Kings Highway East, Haddonfield, NJ 08033
(856) 795-9002 lisa@trrlaw.com

DEFENDANTS

AstraZeneca Pharmaceuticals LP, Aktiebolaget Hassle, AstraZeneca AB, Ranbaxy Pharmaceuticals Inc., Ranbaxy Inc., Ranbaxy Laboratories LTD., Teva Pharmaceutical Industries, LTD., Teva USA, Inc., Dr. Reddy's Laboratories LTD., Dr. Reddy's Laboratories Inc.
County of Residence of First Listed Defendant New Castle County, DE
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Med. Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input checked="" type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from another district (Specify)
☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

15 USC §§1 and 2

Brief description of cause:

Antitrust claims regarding delay of generic competition for brand-named Nexium products.

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

Joel A. Pisano

DOCKET NUMBER

3:12-cv-05443-JAP-TJB

DATE

11/9/12

SIGNATURE OF ATTORNEY OF RECORD

Lisa J. Rodriguez

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE