

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

INTERNATIONAL BROTHERHOOD OF  
ELECTRICAL WORKERS LOCAL 595  
HEALTH AND WELFARE FUND,

Plaintiff,

v.

ASTRAZENECA AB, AKTIEBOLAGET  
HASSLE, ASTRAZENECA LP, RANBAXY  
PHARMACEUTICALS, INC., RANBAXY  
INC., RANBAXY LABORATORIES, LTD.,  
TEVA PHARMACEUTICAL INDUSTRIES,  
LTD., TEVA USA, INC., DR. REDDY'S  
LABORATORIES LTD., and DR. REDDY'S  
LABORATORIES, INC.,

Defendants.

Civil Action No:

**COMPLAINT -- CLASS ACTION**

DEMAND FOR JURY TRIAL

**CLASS ACTION COMPLAINT**

Plaintiff, individually and on behalf of all others similarly situated, alleged as follows. Except as to Plaintiffs' own actions, this complaint is based upon information and belief and the investigation of counsel:

**NATURE OF THE ACTION**

1. This case arises out of alleged anticompetitive agreements designed to shield AstraZeneca and its brand name delayed-release esomeprazole magnesium drug, Nexium, from competition with generic, lower priced versions of the drug. Nexium is a proton pump inhibitor used for treatment of heartburn, erosive esophagitis and gastroesophageal reflux disease (GERD).

2. In 2001 AstraZeneca obtained Food and Drug Administration ("FDA") approval to market and sell prescription delayed-release esomeprazole magnesium under the brand name Nexium. Consistent with the FDA approval process, AstraZeneca submitted a New Drug Application ("NDA") in

which it listed at least thirteen patents on the drug's composition or methods of use. The FDA published this patent information in the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

3. As a result of receiving FDA approval, AstraZeneca has had monopoly power in the market for delayed-release esomeprazole magnesium, controlling 100% of the market, since 2001. By 2005, Nexium emerged as the second best-selling prescription drug in the United States. In 2008, alone, retail sales for Nexium in the United States totaled \$4.8 billion.

4. In 2005 and 2006, three generic drug manufacturers, Ranbaxy, Teva, and Dr. Reddy's (hereinafter, the "Generic Defendants"), sought FDA approval of generic versions of delayed-release esomeprazole magnesium. Consistent with the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, these companies completed Abbreviated New Drug Applications ("ANDA") in which they certified that the proposed generic formulations of the drug did not infringe AstraZeneca's patents for Nexium, and asserted, in part, that AstraZeneca's patents were invalid.<sup>1</sup> The expressed Congressional purpose of the Hatch-Waxman Act is "to make available more low cost generic drugs." H.R. Rep. No. 98-857(I) at 14-15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48. To achieve this purpose, and encourage generic entry and challenges to brand name drug patents, the Act rewards the first company who submits an ANDA by providing a 180-day exclusivity period, triggered on the date the first ANDA applicant begins commercial marketing of its generic drug, during which the FDA will not approve subsequent ANDA applications.

5. Generic versions of brand-name drugs have been determined to be just as safe and effective as their brand-name counterparts. Generic drugs offer substantial consumer benefits, moreover, in that "generic prices can be as much as 90 percent less than brand prices." FTC Staff Study,

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<sup>1</sup> The European patent office previously has found that similar patents registered by AstraZeneca in Europe were invalid.

*Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (FTC, January 2010), at p.1 (available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>) (referred to hereinafter as the “FTC Pay-For-Delay Report”).

6. To protect its annual multi-billion dollar Nexium sales revenue, AstraZeneca entered into pay-for-delay agreements with the Generic Defendants, the details of which are described in paragraphs 67 through 81 below. Under those agreements AstraZeneca agreed to pay the Generic Defendants substantial sums or provide them with other valuable consideration, in exchange for the Generic Defendants’ agreement to drop their patent challenges and refrain from producing and marketing generic formulations of delayed-release esomeprazole magnesium until May 27, 2014 – the very same date the challenged Nexium patents would begin to expire.

7. As a result of these alleged *quid pro quo* arrangements, AstraZeneca and the Generic Defendants agreed to delay the marketing and sale of generic delayed-release esomeprazole magnesium by Ranbaxy, the first ANDA applicant, from approximately April 14, 2008 until May 27, 2014 – a period of just over six years. As a result of similar arrangements with Teva and Dr. Reddy’s, the second and third ANDA-filers, AstraZeneca and Teva and Dr. Reddy’s agreed that Teva and Dr. Reddy’s would also stay out of the market for generic delayed-release esomeprazole magnesium until May 27, 2014, at which point they may be forced to wait another 180 days until Ranbaxy’s exclusivity periods ends.

8. Agreements in which a patent holder provides consideration to, or pays, a would-be generic manufacturer to drop its patent challenge and refrain from producing a generic drug for specific period are commonly known as “reverse payment agreements,” “exclusion agreements,” or “pay-for-delay agreements.” See *FTC Pay-For-Delay Report*, at pp.1, 3. A 2010 analysis by the FTC found that pay-for-delay agreements are a financial “win-win” for the brand name and generic pharmaceutical drug companies that enter into them, yet cost consumers \$3.5 billion annually. See *id.*, at p.2.

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

10. But for one or more of the unlawful pay-for-delay agreements entered into as between AstraZeneca and the Generic Defendants, as alleged herein, generic versions of delayed-release esomeprazole magnesium would have entered the United States market as early as April 14, 2008. Absent Defendants' illegal agreements in restraint of trade, Plaintiff and members of the Class described in paragraph 87, below, would have already been able to purchase, and would have purchased, generic versions of delayed-release esomeprazole magnesium at significantly lower prices, rather than being compelled to pay high prices for brand-name Nexium as a result of Defendants' illegal agreements.

11. Plaintiff brings this action as a class action on behalf of all consumers and third-party payers in the United States and its territories who purchased and/or paid for some or all of the purchase price for brand-name Nexium and/or its generic equivalents, other than for resale, since April 14, 2008 (see Class Definition, paragraph 87, below).

12. Plaintiff seeks a judgment declaring that Defendants' pay-for-delay agreements, as further described below, are unlawful under Section 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 Defendants' anticompetitive agreements. Plaintiff also asserts claims for compensatory and/or treble damages and equitable relief for violations of various state antitrust, consumer protection and unjust enrichment laws.

### **JURISDICTION AND VENUE**

13. Plaintiff brings this action pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover treble damages, equitable relief, costs of suit and reasonable attorneys' fees for Defendants' violations of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1. The Court has subject matter jurisdiction pursuant to Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a), and 28 U.S.C. §§ 1331 and 1337. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

14. Venue is proper in this district under 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b) and (c) because, during the Class Period, the Defendants engaged in interstate commerce and transacted business in this district, and a substantial part of the events giving rise to Plaintiff's claims occurred in this district.

### **PARTIES**

#### **A. Plaintiff**

15. Plaintiff International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund ("IBEW 595 Fund") is a trust fund/employee benefit plan organized under the laws of the United States for the sole and exclusive purpose of providing health and welfare benefits to current, former and retired IBEW 595 union members, and to their dependents and beneficiaries. The IBEW 595 Fund's principal place of business is in Pleasanton, California.

#### **B. Defendants**

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

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

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

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

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

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

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

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

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

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., Bridgewater, New Jersey. 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.

### **TRADE AND COMMERCE**

28. Defendants are among the largest drug manufacturing companies in the world. The relevant product market is delayed-release esomeprazole magnesium. AstraZeneca manufactured this drug under the brand name Nexium. It promoted, distributed, and sold substantial amounts of Nexium across state lines throughout the United States, the relevant geographic market. Defendants regularly conducted business, including contracts, invoices, and other transactions across state lines throughout the country in connection with Nexium and/or bioequivalent generic products.

29. The barriers to entry with respect to the market for delayed-release esomeprazole magnesium are extremely high. As described below, an extensive network of regulatory and patent obstacles must be overcome in order to bring a branded or generic version of a drug, such as delayed-release esomeprazole magnesium, to the market. This is especially true in the case where valid patents related to a particular drug will preclude competitors from entering the market – i.e. from marketing and selling similar drugs – until the expiration of that patent. Both the branded drug and the first generic drug have the ability to exclude other generic competitors from the market.

## **SUBSTANTIVE ALLEGATIONS**

### **A. The Approval and Marketing Process for Brand Name and Generic Drugs**

30. Various laws and regulatory processes strictly regulate the marketing and sale of drugs in the United States. These regulations provide significant incentives for drug companies to be first in line for regulatory approval of their drug. The first company to achieve approval to market and sell a particular drug is known as the “brand name” company and its drug is known as the “brand name” drug. Similar products that receive subsequent approval are known as “generic” versions of the drug. The process also incentivizes drug companies to be the first to gain approval for a generic version of the drug.

31. Defendants have conspired to manipulate this process and abuse these incentives in order to protect AstraZeneca’s exclusive ability to market and sell Nexium, its brand name version of delayed-release esomeprazole magnesium.

#### **1. Brand Name Drugs**

32. A manufacturer that creates a new drug product must obtain FDA approval to market and sell that drug by filing a NDA. Under the Federal Food, Drug, and Cosmetic Act, the NDA must include specific information about the new drug product, including information regarding safety and effectiveness. See 21 U.S.C. §§ 301-392. When the FDA approves an NDA for a new drug product, it becomes known as the “brand name” version of the drug.

33. The NDA must also identify any patents that the brand name drug manufacturer believes apply to the new drug product and that it could assert against another manufacturer who makes, uses, or sells a version of the branded drug prior to the expiration of the patents. 21 U.S.C. § 355(b). When the FDA approves a brand name manufacturer’s NDA, the manufacturer lists these patents in an FDA-maintained registry referred to as the “Orange Book.” The FDA does not vet a brand name



manufacturer's patent listings, but relies entirely on the manufacturer's representation regarding the validity and applicability of the listed patents.

## **2. Generic Drugs**

34. Drug manufacturers wishing to gain subsequent approval for generic versions of the brand name drug need not follow the lengthy and costly NDA filing and approval process. Instead, a generic manufacturer seeking approval to market and sell a generic version of a brand name drug only needs to file an ANDA. *See* FDCA, Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Amendments").

35. The ANDA relies on the safety and effectiveness information provided by the brand name drug manufacturer in the original NDA filing. The generic drug manufacturer must show that the generic drug contains the same active ingredients, dosage form, route administration, and strength as the brand name drug. In short, the generic drug manufacturer must show that the generic drug is pharmaceutically equivalent and bioequivalent to the brand name drug. The FDA assigns generic drugs that are therapeutically equivalent and bioequivalent to their brand name counterpart an "AB" rating.

### **a. Patent Infringement Certification**

36. In order to obtain final FDA approval of an ANDA, a generic drug manufacturer must certify that the generic drug does not infringe any patents listed in the Orange Book by the brand name drug manufacturer. This certification must contain one of four certifications:

- a. that no patent for the brand name drug has been filed with the FDA;
- b. that the patent for the brand name drug has expired;
- c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or
- d. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product ("Paragraph IV Certification").

37. If a generic drug manufacturer files a Paragraph IV Certification, the brand name drug manufacturer can challenge the certification in court by arguing that its patents are valid and/or will be infringed by the generic drug. If the brand name manufacturer brings such an action, the FDA will stay final approval of the ANDA. Instead, the FDA may grant “preliminary approval” to the ANDA, but this does not authorize the generic manufacturer to begin marketing or selling its generic drug product. Preliminary approval is given when the FDA finds that the ANDA would be granted final approval absent the stay of final approval. The FDA gives final approval of the ANDA, and the stay is lifted, at the earlier of: (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid and not infringed by the generic manufacturer’s ANDA.

38. Under this procedure, a brand name manufacturer can delay the final approval of a generic drug by initiating a patent lawsuit and trigger a stay of the generic drug ANDA approval. This allows brand name manufacturers to “game the system” by listing patents in the Orange Book, regardless of whether those patents are valid or applicable, in order to create litigation that will delay the entry of generic drugs into the market for at least 30 months (or the issuance of a court decision, if sooner).

39. However, as long as the generic drug manufacturer continues to press its claims and has not lost in the patent infringement litigation, this delay can last a maximum of 30 months, at which time the FDA will grant final approval of the ANDA. If the FDA grants final approval of a generic drug, the generic manufacturer can begin marketing and selling that drug. However, if the patent litigation is ongoing, such a launch is considered “at risk” because the generic company could incur significant liability if the litigation results in a finding that the brand name manufacturer’s patents were valid and that the generic drug infringed those patents.

**b. The 180-Day Exclusivity Window for the First-Filing Generic Drug**

40. The first generic manufacturer to file an ANDA that includes a Paragraph IV Certification typically receives a 180-day period of exclusive rights to market and sell generic versions of the brand name drug. During this time, the first-filing generic manufacturer is the exclusive provider of generic versions of the drug.

41. This grant of exclusive generic marketing and sales rights allows the first-filing generic manufacturer to control when subsequent generic drug manufacturers may enter the market. If the first-filing generic manufacturer delays its own marketing and sales of the drug, that will delay market entry by other generic manufacturers, who must wait until the expiration of the 180-day period before bringing their generic versions of the drug to market. This tactic of delaying the beginning of the 180-day period, and thus preventing other generic manufacturers from entering the market, is known as “parking.” This creates a “bottleneck,” where other generic manufacturers must wait for the first-filing manufacturer to bring its drug to the market and begin the running of the 180-day period of exclusivity. The brand name drug manufacturer benefits significantly from this parking and corresponding bottleneck because it prevents all generic competitors from marketing and selling generic versions of the brand-name drug.

**c. Forfeiture of the 180-Day Exclusivity Window**

42. The first-filing generic’s 180-day window of exclusive rights is not absolute or guaranteed. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) outlines a number of circumstances in which a first-filing generic forfeits its eligibility for the 180-day exclusivity window. Such forfeiture allows for other generic manufacturers who file ANDAs to bring the generic drugs to market.

43. Under the “failure to market” provision of the MMA, the first-filing generic manufacturer forfeits its 180-day exclusivity window if it fails to begin marketing its drug by the later of:

- a. the earlier of:
  1. 75 days after receiving final FDA approval; or
  2. 30 months after the date it submitted its ANDA; or
- b. 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity, at least one of the following has occurred:
  1. a final decision of invalidity or non-infringement;
  2. a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or
  3. the NDA holder (i.e. the brand-name drug manufacturer) delists the patent from the Orange Book

44. If one of these circumstances occurs, the first-filing generic manufacturer will forfeit its exclusive right to market generic versions of the drug, and other ANDA-filing generic manufacturers will be able to enter the market.

**d. Pay-for-Delay Agreements Enable Brand Name Manufacturers and First-Filing Generics to Avoid Forfeiture of the 180-Day Exclusivity Window and Delay Generic Competition**

45. Typically, brand-name drug companies challenge the first-filing generic manufacturers’ certification that the generic product does not infringe the relevant patents or that the relevant patents are invalid, and litigation ensues between the brand-name and generic manufacturers to determine whether the relevant patents are invalid or infringed. For the brand-name manufacturer to prevail and block the generic’s entry into the market, it must successfully defend the validity of its patents and demonstrate that the generic’s products would infringe those patents. According to a 2002 study by the FTC, generic manufacturers prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and 2002. *FTC Pay-For-Delay Report*, at p.3

46. Brand-name manufacturers and first-filing generics are able to structure settlements of patent litigation in order to avoid triggering the MMA's "failure to market" forfeiture provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before the court enters a final judgment of invalidity or non-infringement with respect to the patents subject to the Paragraph IV Certification. The parties could also seek a consent judgment that does not include a finding that all of the patents subject to the Paragraph IV Certification were invalid or infringed. Such patent litigation settlement agreements ("Agreements" or "Pay-for-Delay Agreements") are at the heart of pharmaceutical patent anti-trust litigation, as is the case here.

47. Avoiding the forfeiture provisions of the MMA in these ways allows the first-filing generic manufacturer to continue delaying bringing its generic product to market, preventing other generics from bringing their generic products to market as well and perpetuating the generic drug bottleneck. In order to then trigger the forfeiture provisions and gain access to the market, other generic manufacturers that filed subsequent ANDAs must get a court judgment that all of the patents covered by the first-filing generic manufacturer's Paragraph IV Certification are invalid or not infringed. This likely requires the subsequent generic manufacturer to bring a declaratory judgment action over patents that the brand name manufacturer did not assert against it. The follow-on litigation can be resolved by a similarly structured settlement, thereby perpetuating the 180-day bottleneck and further delaying generic competition.

### **3. Generic Competition Benefits Consumers**

48. Generic drugs offer substantial consumer benefits. Generics that are therapeutically equivalent to their brand-name counterpart frequently cost less than the brand-name drug. According to the FTC, "generic prices can be as much as 90 percent less than brand prices." *FTC Pay-For-Delay Report*, at p.1. Given these cost savings, pharmacists are permitted (and, in some states, required) to

substitute a generic drug for a brand-name product prescribed, unless the prescribing physician has indicated that the prescription for the brand-name drug must be “dispensed as written.”

49. 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. And 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% to 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.

50. However, until a generic version of the brand name drug enters the market, there is no therapeutically equivalent generic drug to substitute for and compete with the brand name drug, and therefore the brand name manufacturer can continue to charge higher prices for the drug without losing all or a substantial portion of its brand name sales. Consequently, brand-name drug manufacturers, who are well aware of generic companies’ rapid erosion of their brand name sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements alleged above and below.

#### **B. AstraZeneca’s Nexium NDA Approval**

51. Nexium is a proton pump inhibitor that is available by prescription only, and is used to treat heartburn, erosive esophagitis and gastroesophageal reflux disease (GERD). The active ingredient in Nexium is esomeprazole magnesium, which is introduced into the body through oral consumption of delayed-release capsules. Nexium’s pharmacological profile, and thus its side effects and efficacy profile, is different than other proton pump inhibitors and non-prescription antacids that are used to treat

similar conditions. Drugs that are not the therapeutic equivalent and bioequivalent of Nexium cannot be substituted for Nexium by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Nexium, and thus are not economic substitutes for, nor reasonably interchangeable with, Nexium.

52. On December 3, 1999, AstraZeneca submitted NDA 21-153 seeking FDA approval to market esomeprazole magnesium delayed-release capsules in 20mg and 40mg doses under the brand name Nexium. The FDA approved AstraZeneca's NDA for Nexium on February 20, 2001.

53. In connection with its NDA, AstraZeneca listed at least thirteen patents for Nexium in the FDA Orange Book ("Nexium patents"). Although the Nexium patents purport to cover, among other things, compounds and pharmaceutical compositions comprised of magnesium salts of esomeprazole, and the delayed-release and other methods of using those compounds and composition, certain of the patents were particularly susceptible to challenge from generic manufacturers due to their similarity to prior science and products, namely AstraZeneca's prior proton pump inhibitor drug, Prilosec.

54. Thus, 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 again in 2011, in connection with opposition proceedings brought by generic manufacturers, that two European Nexium patents—which are similar to U.S. Nexium patents—were invalid and thus revoked for failing to satisfy the "inventive step" requirement, which is analogous to the obviousness standard under U.S. patent law (requiring that an invention not be obvious, in light of existing science, to a person of ordinary skill in the relevant scientific field at the time the patent for the invention was filed).

### **C. AstraZeneca's Market and Monopoly Power**

55. As a result of its achieving FDA approval of Nexium and filing related patents, AstraZeneca has had monopoly power in the market for delayed-release esomeprazole magnesium,

controlling 100% of the market. As a result of this monopoly power, which was maintained through the Defendants' conduct, AstraZeneca has been able to sell Nexium in a competitive vacuum and at higher prices well above marginal costs.

56. Nexium has been the second best-selling prescription drug in the United States since 2005. In 2008, U.S. retail sales for Nexium totaled \$4.8 billion.

57. Nexium does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than generic versions of Nexium. Other drugs that are not therapeutically equivalent and bioequivalent to Nexium are not considered substitutes for Nexium. Nexium, and bioequivalent versions of Nexium, are differentiated from other products because their ability to treat erosive esophagitis, maintain the healing of erosive esophagitis, and treat symptomatic gastroesophageal reflux disease.

58. Due to this differentiation, AstraZeneca has not needed to control any products other than Nexium and its generic equivalents in order to maintain the high prices of Nexium. Only FDA approved, bioequivalent generic versions of Nexium would act as competitive substitutes for Nexium and threaten its dominant market position.

**D. The Generic Defendants Sought to Gain Approval of Generic Versions of Nexium**

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 delayed-release esomeprazole magnesium in 20 mg and 40 mg capsules. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic delayed-release esomeprazole magnesium product would not infringe any valid claim of any patent that expired after October 2007 listed in the FDA Orange Book as covering Nexium or a method of using Nexium.



60. On November 21, 2005, AstraZeneca sued Ranbaxy in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Ranbaxy's generic version of delayed-release esomeprazole magnesium would infringe six of AstraZeneca's Nexium patents, five of which were listed in the FDA Orange Book: 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 25, 2006, IVAX Pharmaceuticals, Inc., now owned by Generic Defendant Teva, notified AstraZeneca that it had filed ANDA No. 78-003, seeking to market generic versions of delayed-release esomeprazole magnesium in 20 mg and 40 mg capsules. The notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of any patent listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

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

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 delayed-release esomeprazole magnesium in 20 mg and 40 mg 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 delayed-release esomeprazole magnesium product would not infringe the '504, '192 or '872 patents, or that those patents were invalid.

64. On January 17, 2008, AstraZeneca sued Dr. Reddy in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Dr. Reddy's generic versions of delayed-release esomeprazole magnesium 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 versions of delayed-release esomeprazole magnesium 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 Pay-For-Delay Agreements, as described below, before any substantive challenges to AstraZeneca's patents were ultimately resolved by the court.

66. To prevent generic entry using just its patents (rather than pay-offs), AstraZeneca would have had to show that each of the generic versions of delayed-release esomeprazole magnesium infringed its patents for Nexium, and to defeat each of the Generic Defendants' invalidity arguments. AstraZeneca instead decided to protect its monopoly by paying the Generic Defendants to withdraw their challenges to the validity and enforceability of its Nexium patents, and to delay their introduction, marketing and sale of generic delayed-release esomeprazole magnesium.

**E. AstraZeneca Paid Ranbaxy to Delay Its Release of a Generic Delayed-Release Esomeprazole Magnesium**

67. On or about April 14, 2008, AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy 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 same day that the 30-month stay of FDA approval of Ranbaxy's generic delayed-release esomeprazole magnesium product expired.

68. Under the AstraZeneca/Ranbaxy Agreement, Ranbaxy agreed to: (a) admit that the '504, '192, '789, '085, '810 and '872 patents were enforceable and valid; (b) admit that its generic versions of delayed-release esomeprazole magnesium products would infringe the '504, '192, '789 and '872 patents; and (c) delay launching its generic delayed-release esomeprazole magnesium 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 delayed-release esomeprazole magnesium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to designate Ranbaxy as a manufacturer of AstraZeneca's US supply of Nexium, resulting in significant revenue for Ranbaxy. Shortly after AstraZeneca and Ranbaxy entered the Agreement, Ranbaxy's Chief Executive Officer, Malvinder Singh, boasted that the Agreement would give Ranbaxy as much as *\$1.5 billion* in revenue between the date of the Agreement and the end of its 180-day marketing exclusivity in 2014. Singh characterized the Agreement as the biggest and most comprehensive settlement to date by any generic company globally. Upon information and belief, AstraZeneca has already paid Ranbaxy millions of dollars under their Agreement.

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 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 delayed market entry of generic forms of delayed-release esomeprazole magnesium.

71. Ranbaxy's ANDA received tentative approval on February 5, 2008 and, absent the AstraZeneca/Ranbaxy Agreement, would have received final approval on or about April 14, 2008, the date the 30-month stay of FDA approval expired, at which point Ranbaxy would have needed to take its generic drug to market or forfeit its 180-day window of exclusivity. Either result would have uncorked the bottleneck that has prevented generic versions of delayed-release esomeprazole magnesium from entering the market.

**F. AstraZeneca Paid Teva and Dr. Reddy's to Delay Their Release of Generic Delayed-Release Esomeprazole Magnesium**

**1. The AstraZeneca and Teva Pay-For-Delay Agreement**

72. On April 30, 2008, shortly after AstraZeneca and Ranbaxy entered their Agreement, Generic Defendant Teva filed a declaratory judgment action against AstraZeneca seeking a ruling of invalidity and non-infringement regarding the remaining Orange Book-listed patents that AstraZeneca did not sue Teva for infringing in connection with Teva's generic delayed-release esomeprazole magnesium ANDA. The goal was to 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.

73. In response to AstraZeneca's motion to dismiss the declaratory judgment action for lack of jurisdiction, Teva accused AstraZeneca of gaming the system "to take advantage of what [Teva] contends is an *invalid and illegitimate patent monopoly*." According to Teva, as a result of the AstraZeneca/Ranbaxy 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."

74. On or about January 7, 2010, AstraZeneca and Teva entered into the AstraZeneca/Teva Agreement, which ended the litigation between AstraZeneca and Teva and delayed entry of Teva's generic delayed-release esomeprazole magnesium products until at least May 27, 2014 unless specifically authorized by the Agreement.

75. As the *quid pro quo* for Teva's agreement to drop its challenge to the Nexium patents and to delay entry of its generic delayed-release esomeprazole magnesium products until at least May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Teva by forgiving a massive contingent liability that Teva potentially owed to AstraZeneca. In September 2004, Teva had commenced an "at risk" launch of generic Prilosec, which was manufactured by its marketing partner Impax. In 2008, the Federal Circuit affirmed the district court's ruling that the Prilosec patents were valid and infringed by Impax's generic Prilosec product. Because Teva had brought the generic drug to market in conjunction with Impax, there was a substantial risk that Teva would owe AstraZeneca potentially massive infringement damages resulting from years of infringing AstraZeneca's Prilosec patents. As part of and

simultaneously with the AstraZeneca/Teva Agreement, Teva and AstraZeneca agreed that (1) Teva would make a one-time payment to AstraZeneca that AstraZeneca characterized as not financially material to account for its past infringing Prilosec sales, and (2) AstraZeneca would forgive Teva's potential massive Prilosec liability.

76. The true purpose and effect of AstraZeneca's payment to Teva – the forgiveness of Teva's potential Prilosec liability – was to delay generic competition to Nexium until May 27, 2014. Absent Teva's agreement to delay entry into the market with generic versions of delayed-release esomeprazole magnesium, 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.

## **2. The AstraZeneca and Dr. Reddy's Pay-For-Delay Payment Agreement**

77. On or about January 28, 2011, AstraZeneca and Dr. Reddy's entered the AstraZeneca/Dr. Reddy's Agreement, which ended the litigation between AstraZeneca and Dr. Reddy's and delayed entry of Dr. Reddy's generic delayed-release esomeprazole magnesium products until at least May 27, 2014 unless specifically authorized by the Agreement. Dr. Reddy's made no admissions regarding validity or infringement.

78. 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 at least May 27, 2014, AstraZeneca agreed to pay Dr. Reddy's by forgiving Dr. Reddy's from an outstanding contingent liability. Dr. Reddy's had launched its generic version of AstraZeneca's Accolate product "at risk." in November 2010, following a summary judgment opinion which held that Dr. Reddy's generic products did not infringe AstraZeneca's Accolate-related patents. AstraZeneca appealed that decision, but in late January 2011 – the same time Dr. Reddy's agreed to end its Nexium litigation – AstraZeneca agreed to dismiss the appeal. By agreeing, as part of and simultaneously with the AstraZeneca/Dr. Reddy's 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.

79. 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 versions of delayed-release 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 delayed market entry of generic delayed-release esomeprazole magnesium.

80. By paying Teva and Dr. Reddy's not to market their generic delayed-release esomeprazole magnesium products before May 27, 2014 – the day the Nexium patents at issue were to begin to expire – 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.

81. The generic manufacturers seeking to sell generic versions of delayed-release esomeprazole magnesium have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and 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. Absent the Pay-For-Delay Agreements, generic manufacturers could have, and would have, brought inexpensive generic versions of delayed-release esomeprazole magnesium to market as soon as April 14, 2008.

**G. Antitrust Impact and the Anticompetitive Effects of Defendants' Conduct**

82. The Pay-For-Delay Agreements harmed Plaintiff and the Class by depriving them of a market in which generic competition is not restrained or delayed by payments to would-be competitors. Contrary to the purpose of the Hatch-Waxman Act, the Pay-For-Delay Agreements have enabled AstraZeneca and the Generic Defendants to: (a) prevent and delay the entry of less expensive generic versions of Nexium in the United States; (b) fix, raise, maintain or stabilize the price of delayed-release esomeprazole magnesium products; (c) permit AstraZeneca to maintain a monopoly in the U.S. market for delayed-release esomeprazole magnesium products; and (d) allocate 100% of the U.S. market for delayed-release esomeprazole magnesium to AstraZeneca.

83. Moreover, due to Defendants' Pay-For Delay Agreements, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of delayed-release esomeprazole magnesium, and/or (b) challenging the validity or infringement of the Nexium patents in court.

84. But for the Pay-For Delay Agreements, end-payors, such as Plaintiff and members of the Class, would have paid less for delayed-release esomeprazole magnesium by (a) substituting purchases of less-expensive generic delayed-release esomeprazole magnesium for their purchases of more expensive branded Nexium, (b) receiving discounts on their remaining branded Nexium purchases, and (c) purchasing generic Nexium at lower prices sooner.

85. During the Class Period, Plaintiff and other members of the Class 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 delayed-release esomeprazole magnesium and were deprived of the opportunity to purchase lower-priced generic Nexium instead of expensive brand-name Nexium. As a consequence, Plaintiff and other members of



the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

86. The prices were inflated as a direct and foreseeable result of AstraZeneca's anticompetitive conduct individually and with Generic Manufacturers. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and the Generic Manufacturers.

### **CLASS ACTION ALLEGATIONS**

87. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of an 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, insured, participants, or beneficiaries (the "Class" or the "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.

88. The following persons or entities are excluded from the proposed End-Payor Class:
- 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.

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

90. Plaintiff’s claims are typical of the claims of the members of the End-Payor Class. Plaintiff and all members of the End-Payor Class 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.

91. Plaintiff will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the End-Payor Class. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation.

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

93. Questions of law and fact common to the End-Payor Class 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 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 Nexium;
- g. whether AstraZeneca's compensation to the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and nonpretextual;
- h. whether the Agreements created a bottleneck to generic competition;
- i. whether one or more of the Agreements is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;
- j. whether AstraZeneca possessed monopoly power over Nexium;
- k. 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;
- l. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- m. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and
- n. the quantum of aggregate overcharge damages to the Class.

94. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated 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.

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

**COUNT I**  
**(VIOLATIONS OF 15 U.S.C. §§ 1 AND 2)**  
**(ASSERTED AGAINST ASTRAZENECA AND RANBAXY; ASTRAZENECA AND TEVA;**  
**AND ASTRAZENECA AND DR. REDDY'S)**

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

97. The Pay-For-Delay Agreements between AstraZeneca and each of the Generic Defendants involve: (a) a payment from AstraZeneca to the respective Generic Defendant; and (b) an agreement by the Generic to delay marketing its generic delayed-release esomeprazole magnesium 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 their generic delayed-release esomeprazole magnesium 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 delayed-release esomeprazole magnesium Nexium until May 27, 2014.

98. The purpose and effect of the unlawful Pay-For-Delay Agreements between AstraZeneca and each of the Generic Defendants was to allocate 100% of the delayed-release esomeprazole magnesium market in the United States to AstraZeneca; delay the sales of generic delayed-release esomeprazole magnesium products for up to over six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for delayed-release esomeprazole magnesium at the higher, branded price.

99. Each of the Pay-For-Delay Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

100. Each of the Pay-For-Delay 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 Pay-For-Delay 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.

101. In addition, through the Pay-For-Delay 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 delayed-release esomeprazole magnesium products from the market for as long as six years or more.

102. 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. The goal, purpose and/or effect of the Pay-For-Delay Agreements were to maintain and extend AstraZeneca’s monopoly power in the United States market for delayed release esomeprazole magnesium in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Pay-For-Delay Agreements prevented and/or delayed generic competition to Nexium and enabled AstraZeneca to continue charging higher prices for Nexium without a substantial loss of sales.

103. AstraZeneca and the Generic Defendants knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market.

104. AstraZeneca and the Generic Defendants specifically intended that the Pay-For-Delay Agreements would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

105. AstraZeneca and the Generic Defendants each committed at least one overt act in furtherance of the conspiracy.

106. 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 Class were harmed as described herein.

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

108. Plaintiff and the Class further seeks 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**  
**(VIOLATION OF STATE ANTITRUST LAWS – CONSPIRACY TO MONOPOLIZE)**  
**(ASSERTED AGAINST ASTRAZENECA AND RANBAXY; ASTRAZENECA AND TEVA;**  
**AND ASTRAZENECA AND DR. REDDY'S)**

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

110. 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.

111. Through the Pay-For-Delay 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 delayed-release esomeprazole magnesium products from the market for as long as six years or more in violation of Section 2 of the Sherman Act. The Pay-For-Delay Agreements between AstraZeneca and each of the Generic Defendants allocated 100% of the delayed-release esomeprazole magnesium market in the United States to AstraZeneca; delayed the sales of generic delayed-release esomeprazole magnesium products for up to over six years; and fixed the price at which consumers and other End-Payor Plaintiffs would pay for delayed-release esomeprazole magnesium at the higher, branded price.

112. AstraZeneca and the Generic Defendants specifically intended that the Pay-For-Delay Agreements would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

113. AstraZeneca and the Generic Defendants each committed at least one overt act in furtherance of the conspiracy.

114. 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 Class paid artificially inflated prices for their delayed-release esomeprazole magnesium requirements as described herein, and were harmed as a result.

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

- a. Defendants have intentionally and wrongfully engaged in 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 Class.

- b. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. 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 conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Kansas by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Maine by members of the Class.
- g. Defendant have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Massachusetts by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. 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.
- i. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Minnesota by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. 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.



- k. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Nebraska by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. 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 higher prices caused by Defendants' conduct.
- m. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New Mexico by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New York by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. 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.
- p. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.D. 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.
- q. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Oregon by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in South Dakota by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. 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.

- t. Defendants have intentionally and wrongfully engaged in 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.
- u. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Vermont by members of the Class.
- v. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in West Virginia by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. 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.

116. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release esomeprazole magnesium products, and (2) paying higher prices for delayed-release 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 and the District of Columbia were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

117. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**COUNT III**  
**(VIOLATION OF STATE ANTITRUST LAWS – CONSPIRACY AND COMBINATION IN**  
**RESTRAINT OF TRADE)**  
**(ASSERTED AGAINST ASTRAZENECA AND RANBAXY; ASTRAZENECA AND TEVA;**  
**AND ASTRAZENECA AND DR. REDDY’S)**

118. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein. The Pay-For-Delay Agreements between AstraZeneca and each of the Generic Defendants involve: (a) a payment from AstraZeneca to the respective Generic Defendant; and (b) an agreement by the Generic to delay marketing its generic delayed-release esomeprazole magnesium products 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 their generic versions of generic delayed-release esomeprazole magnesium 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 delayed-release esomeprazole magnesium until May 27, 2014.

119. 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.

120. The purpose and effect of the unlawful Pay-For-Delay Agreements between AstraZeneca and each of the Generic Defendants was to allocate 100% of the delayed-release esomeprazole magnesium market in the United States to AstraZeneca; delay the sales of generic delayed-release esomeprazole magnesium products for up to over six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for delayed-release esomeprazole magnesium at the higher, branded price.

121. Each of the Pay-For-Delay Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

122. 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 Class paid artificially inflated prices for their delayed-release esomeprazole magnesium requirements as described herein, and were harmed as a result.

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

- a. Defendants have intentionally and wrongfully engaged in a 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 Class.
- b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. 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 Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Kansas by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Maine by members of the Class.

- g. Defendant have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Massachusetts by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. 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.
- i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Minnesota by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. 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.
- k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Nebraska by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. 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 higher prices caused by Defendants' conduct.
- m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New Mexico by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New York by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. 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.

- p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. 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.
- q. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Oregon by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in South Dakota by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. 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.
- t. 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.
- u. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Vermont by members of the Class.
- v. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in West Virginia by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. 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.

124. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release esomeprazole magnesium products, and (2) paying higher prices for delayed-release 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 and the District of Columbia were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

125. Plaintiff and the Class seek compensatory and/or treble damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**COUNT IV**  
**(VIOLATION OF STATE UNFAIR AND DECEPTIVE TRADE PRACTICES LAWS)**  
**(ASSERTED AGAINST ALL DEFENDANTS)**

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

127. 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 class members 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 acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Arizona by members of the Class.
- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect



to purchases of Nexium and AB-rated generic equivalents in California by members of the Class.

- c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Florida by members of the Class.
- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Illinois by members of the Class.
- e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Kansas by members of the Class.
- f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Maine by members of the Class.
- g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Nexium and AB-rated generic equivalents in actions and transactions occurring substantially within Massachusetts.
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Michigan by members of the Class.
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Minnesota by members of the Class.
- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Nebraska by members of the Class.
- k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*, with respect to



purchases of Nexium and AB-rated generic equivalents in Nevada by members of the Class.

- l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New Hampshire by members of the Class.
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New Mexico by members of the Class.
- n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in New York by members of the Class.
- o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in North Carolina by members of the Class.
- p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in South Dakota by members of the Class.
- q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Tennessee by members of the Class.
- r. 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 generic equivalents in Utah by members of the Class.
- s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451 *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in Vermont by members of the Class.
- t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*, with respect to purchases of Nexium and AB-rated generic equivalents in West Virginia by members of the Class.

128. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Nexium and/or AB-rated generic equivalents 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.

**COUNT V**  
**(UNJUST ENRICHMENT)**  
**(ASSERTED AGAINST ALL DEFENDANTS)**

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

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

131. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for delayed-release esomeprazole magnesium by Plaintiff and members of the Class.

132. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

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

134. It would be futile for Plaintiff and the 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.

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

136. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

137. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to be permitted to retain any of the overcharges for Nexium and/or AB-rated generic equivalents derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

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

139. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

140. Plaintiff and the Class have no adequate remedy at law.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Class, 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 Class and declare the Plaintiff representative of the End-Payor Class;

B. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

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 Class;

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

F. Award the 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 Class 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.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury on those claims that can be tried to a jury.

DATED: October 16, 2012

Respectfully submitted,

By: 

Steven A. Asher

Mindee J. Reuben

**WEINSTEIN KITCHENOFF & ASHER LLC**

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Philadelphia, PA 19103

Telephone: (215) 545-7200

Facsimile: (215) 545-6535

Email: [asher@wka-law.com](mailto:asher@wka-law.com);

[reuben@wka-law.com](mailto:reuben@wka-law.com)

By: /s/ Elizabeth C. Pritzker (Pro Hac Vice to be filed)

Eric H. Gibbs (Pro Hac Vice to be filed)

Scott M. Grzencyk (Pro Hac Vice to be filed)

**GIRARD GIBBS LLP**

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Todd M. Schneider (Pro Hac Vice to be filed)

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Aaron Kaufmann (Pro Hac Vice to be filed)

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Oakland, CA 94612

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Facsimile: (510) 272-0174

Email: [akaufmann@leonardcarder.com](mailto:akaufmann@leonardcarder.com)

*Counsel for International Brotherhood of Electrical  
Workers Local 595 Health and Welfare Fund*

JS 44 (Rev. 09/11)

## CIVIL COVER SHEET

12-cv-5916

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

INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS  
LOCAL 595 HEALTH AND WELFARE FUND

(b) County of Residence of First Listed Plaintiff: Alameda County, CA  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number):  
Weinstein Kitchenoff & Asher LLC, 1845 Walnut Street, Suite 1100,  
Phila., PA 19096, 215 545 7200; Girard Gibbs LLP, 601 California St.,  
14th Fl., San Francisco, CA 415 981 4800; et al.

## DEFENDANTS

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP,  
RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., RANBAXY  
LABORATORIES, LTD., TEVA PHARMACEUTICAL IND., et al.

County of Residence of First Listed Defendant: Soderalje, Sweden  
(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
- ☒ 2 Federal Question  
(U.S. Government Not a Party)
- ☐ 3 U.S. Government Defendant
- ☐ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES

(For Diversity Cases Only)

(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 type="checkbox"/> 4 |
| Citizen of Another State                | <input 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	<b>PERSONAL INJURY</b> <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	<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 <b>PERSONAL PROPERTY</b> <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 <b>LABOR</b> <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	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <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)) <b>FEDERAL TAX SUITS</b> <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"/> 430 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
<b>REAL PROPERTY</b> <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	<b>CIVIL RIGHTS</b> <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	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <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 U.S.C. Section 1, 2

Brief description of cause:  
Agreements to Restrain Competition

## 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 Hon. Legrome D. Davis

DOCKET NUMBER 12-cv-04893

DATE

10/16/2012

SIGNATURE OF ATTORNEY OF RECORD

Mindee G. Reuben

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAJ. JUDGE

OCT 16 2012



**FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM** to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund, 7180 Koli Center Parkway, Suite 200, Pleasanton, CA 94566

Address of Defendant: (First U.S. Defendant) AstraZeneca LP, 1800 Concord Pike, Wilmington, DE 19803

Place of Accident, Incident or Transaction: Nationwide

(Space)

(Use Reverse Side For Additional

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes ☒ (Def.) No

Does this case involve multidistrict litigation possibilities?

Yes ☒ No

**RELATED CASE, IF ANY:**

Case Number: 12-cv-4893 Judge Hon. Leqrome D. Davis Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☒ No ☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place    in ONE CATEGORY ONLY)

**A. Federal Question Cases:**

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☒ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. All other Federal Question Cases

**B. Diversity Jurisdiction Cases:**

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify)

**ARBITRATION CERTIFICATION**

(Check appropriate Category)

I, Mindie Reuben, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;

Relief other than monetary damages is sought.

DATE: Oct. 16, 2012

Mindie J. Reuben  
Attorney-at-Law

75308

Attorney I.D.#

**NOTE:** A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: Oct. 16, 2012

Mindie J. Reuben  
Attorney-at-Law

75308

Attorney I.D.#

Attachment

Related Cases

There is currently a request to transfer and coordinate proceeding before the Judicial Panel on Multidistrict Litigation, MDL #2409. The cases that are part of that proceeding are:

- Fraternal Order of Police Miami Lodge 20, Insurance Trust Fund v. Astrazeneca LP et al, Eastern District of Pennsylvania, 2012-cv-04893, Judge Legrome D. Davis
- Rochester Drug Co-Operative, Inc. v. Astrazeneca AB et al., Eastern District of Pennsylvania, 2012-cv-04911, Judge Legrome D. Davis
- New York Hotel Trades Council & Hotel Association of New York City, Inc., Health Benefits Fund v. Astrazeneca AB et al., Eastern District of Pennsylvania, 2012-cv-04898, Judge Paul S. Diamond
- Meijer, Inc., et al v. Astrazeneca AB et al., District of New Jersey, 2012-cv-05443, Judge Joel A. Pisano
- Value Drug Company, et al. v. Astrazeneca PLC. et al., District of New Jersey, 2012-cv-05525, Judge Joel A. Pisano
- International Union of Machinists and Aerospace Workers District No. 15 Health Fund v. Astrazeneca, District of New Jersey, 2012-cv-05938, Judge Joel A. Pisano
- Professional Drug Company, Inc. v. Astrazeneca AB et al, District of Massachusetts, 2012-cv-11609, Judge William G. Young
- American Sales Company, LLC v. Astrazeneca AB et al, District of Massachusetts, 2012-cv-11711, Judge William G. Young



**LDD**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

INTERNATIONAL BROTHERHOOD OF  
ELECTRICAL WORKERS LOCAL 595  
HEALTH AND WELFARE FUND,

Plaintiff,

v.

ASTRAZENECA AB, AKTIEBOLAGET  
HASSLE, ASTRAZENECA LP, RANBAXY  
PHARMACEUTICALS, INC., RANBAXY  
INC., RANBAXY LABORATORIES, LTD.,  
TEVA PHARMACEUTICAL INDUSTRIES,  
LTD., TEVA USA, INC., DR. REDDY'S  
LABORATORIES LTD., and DR. REDDY'S  
LABORATORIES, INC.,

Defendants.

Civil Action No: **12 5916**

**COMPLAINT -- CLASS ACTION**

**DEMAND FOR JURY TRIAL**

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

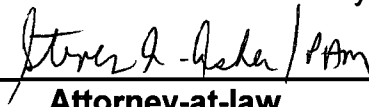
by 16 2012

(x)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

October 16, 2012

Date

  
Attorney-at-law

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