UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:13-cv-09244-RA-RLE

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. End-Payor Plaintiffs, United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, Crosby Tugs, LLC, Insurance Trust Fund, International Union of Operating Engineers Local 132 Health and Welfare Fund, NECA-IBEW Welfare Trust Fund, City of Providence, Rhode Island, Painters District Council No. 30 Health and Welfare Fund, Minnesota and North Dakota Bricklayers and Allied Craftworkers Health Fund, New England Electrical Workers Benefits Fund, MAN-U Service Contract Trust Fund, and 199SEIU National Benefit Fund on behalf of themselves and all others similarly situated, file this Consolidated Amended Class Action Complaint against Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"), Mylan Inc. and Mylan Pharmaceuticals, Inc., (together, "Mylan"), Actavis plc f/k/a Actavis, Inc. and Watson Laboratories, Inc. (together, "Actavis"), Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc., (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together, "Teva"). Defendants Mylan, Actavis, Ranbaxy, and Teva will collectively be referred to as the "Generic Defendants." Takeda and the Generic Defendants will collectively be referred to as the "Defendants." Based upon personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, the End-Payor Plaintiffs allege as follows:

II. NATURE OF THE ACTION

2. This action arises out of Defendants' overarching anticompetitive scheme to allocate, and unreasonably delay competition in, the market for pioglitazone hydrochloride tablets, which Takeda sells under the brand name ACTOS, and further anticompetitive

agreements that Takeda entered into with Mylan and Teva to allocate, and unreasonably delay competition in, the market for the fixed dose combination product containing both pioglitazone hydrochloride and metformin (biguanide), which Takeda sells under the brand name ACTO*plus* met. Doctors prescribe ACTOS for the improvement of glycemic control in patients with Type 2 diabetes, either as either a monotherapy treatment or a combination therapy consisting of two separate drugs—pioglitazone hydrochloride together with sulfonylurea, metformin, or insulin. Doctors prescribe ACTO*plus* met as a fixed dose combination of pioglitazone hydrochloride and metformin to improve blood sugar control in adults with Type 2 diabetes who are already taking ACTOS and metformin separately, or taking metformin alone and it is not controlling blood glucose at normal levels.

3. ACTOS became one of Takeda's biggest selling products. By 2011, ACTOS and ACTO*plus* met together generated over $3 billion in annual sales. Takeda knew, however, that the products were vulnerable to a rapid and near-complete loss of sales once less expensive generic versions entered the market.

4. In order to delay the onset of generic competition and squeeze more multi-billion-dollar years out of these products, Takeda devised a multi-part scheme which it enticed its would-be generic competitors to join.

5. First, Takeda submitted false and misleading patent information regarding two patents to the Food and Drug Administration (the "FDA") for publication in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to ACTOS. Takeda asserted in its patent information that the two patents—United States Patent Nos. 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent")—claim the ACTOS drug product. These patents plainly and unambiguously do not claim the ACTOS drug product,

however, because the '584 Patent claims a drug product consisting of pioglitazone hydrochloride *and* a biguanide. Similarly, the '404 Patent claims a drug product consisting of pioglitazone hydrochloride *and* an insulin secretion enhancer.

6. The ACTOS drug product contains neither biguanide nor an insulin secretion enhancer, and thus neither the '584 Patent nor the '404 Patent claims the ACTOS drug product. Indeed, Takeda has listed the '584 Patent in the Orange Book as claiming the drug product ACTO*plus* met, which does contain both pioglitazone hydrochloride and a biguanide, and has listed the '404 Patent in the Orange Book as claiming the drug product Duetact, which does contain both pioglitazone hydrochloride and an insulin secretion enhancer.

7. Among other intended anticompetitive effects, Takeda's submission of false and misleading patent information regarding the '584 Patent and '404 Patent for ACTOS permitted the first generic manufacturer that filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV Certification, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to claim the 180-day exclusivity provided by the Hatch-Waxman Act. That exclusivity prevented the FDA from approving any other generic ACTOS products from entering the market until 180 days after the first-filer entered. Takeda's submission of false and misleading patent information thus created a "bottleneck" on FDA approval of *any* generic ACTOS products until the first generic filer entered the market. Later-filing generic manufacturers were automatically delayed due to the first-filer's 180-day exclusivity.

8. **Second**, Takeda exacerbated the economic harm caused by its false and misleading patent submission by paying the generic first-filers to delay entry. Having created the bottleneck, Takeda paid the first-filers to keep the bottleneck in place.

9. Generic competition for ACTOS was likely to begin immediately after ACTOS's drug substance patent—U.S. Patent No. 4,687,777 (the "'777 Patent")—expired on January 17, 2011. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval to sell generic ACTOS. Defendants Mylan, Ranbaxy, and Actavis were entitled to "shared" 180-day exclusivity for ACTOS. These Defendants had all submitted Paragraph IV Certifications with respect to the '584 Patent and the '404 Patent, and obtained a June 2010 trial date for their allegations that Takeda's patents allegedly covering ACTOS were invalid, unenforceable, or would not be infringed by their generic products. That trial date would have permitted Mylan, Ranbaxy, and Actavis to successfully conclude the patent litigation and enter the market on or about January 17, 2011.

10. Takeda knew there was a substantial risk that its infringement claims would not prevail in the litigation. Therefore, as the trial date approached, Takeda made large, unjustified payments to Mylan, Ranbaxy, and Actavis to withdraw their challenges to the patents and delay entry into the market. In exchange for these Exclusion Payments—*i.e.*, a share of the supracompetitive profits made possible by the absence of generic competition—Mylan, Ranbaxy, and Actavis agreed to delay entering the market until August 17, 2012. As planned, this delayed entry by the first-filers had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after August 17, 2012.

11. **Third**, Takeda repeated this same Exclusion-Payment ploy with respect to ACTO*plus* met. Takeda had listed the '584 Patent as a drug product patent claiming ACTO*plus* met, and had listed various other patents as applicable method-of-use patents. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval

to sell generic ACTO*plus* met. Defendant Mylan submitted the first ANDA with a Paragraph IV Certification with respect to ACTO*plus* met and was thus eligible for the Hatch-Waxman Act 180-day exclusivity.

12. Takeda knew there was a substantial risk that its infringement claims under these patents would not prevail in the litigation. Therefore, as Mylan's Hatch-Waxman Act 30-month stay (21 U.S.C. § 355(j)(5)(B)(iii)) was set to expire, Takeda made large, unjustified payments to Mylan to withdraw its challenge to the patents and delay entry into the market. In exchange for these Exclusion Payments—*i.e.*, a share of the supracompetitive profits made possible by the absence of generic competition—Mylan agreed to delay entering the market until 2012. As planned, this delayed entry by the first-filer had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after Mylan entered.

13. **Fourth**, Takeda and Mylan, Ranbaxy, and Actavis took additional anticompetitive measures to ensure that Defendant Teva did not unravel the anticompetitive schemes they had concocted. Teva had refused to submit a Paragraph IV Certification with respect to the '584 Patent and '404 Patent regarding ACTOS on the ground that Takeda had improperly identified them as drug product patents covering ACTOS. Instead, Teva filed what is known as a "Section viii Statement" (*see* 21 U.S.C. § 355(b)(2)(B) & 21 U.S.C. § 355(j)(2)(A)(viii)), attesting that Teva did not seek FDA approval for a use covered by the patents that Takeda had listed in the Orange Book.

14. Without regard to whether the lawsuit had legal merit, Takeda sued Teva for infringement of the patents allegedly covering ACTOS and ACTO*plus* met. Had Teva prevailed in that lawsuit, it could have entered the market with generic ACTOS upon the expiration of the

'777 Patent on January 17, 2011. Under the Hatch-Waxman Act, and pursuant to the relief that Teva sought in its counterclaims against Takeda, Teva would not have been subject to the 180-day exclusivity bottleneck that Takeda, Mylan, Ranbaxy, and Actavis had constructed and extended.

15. Teva secured a June 2010 trial date, which gave it time to obtain a favorable ruling before January 17, 2011. Rather than risk the unraveling of its anticompetitive scheme and agreements with Mylan, Ranbaxy, and Actavis, Takeda made large, unjustified payments to Teva to withdraw its challenge to the patents, stop contesting Takeda's submission of false patent information regarding the '584 Patent and '404 Patent for ACTOS, and delay entry into the market. In exchange for these Exclusion Payments—i.e., a share of the supracompetitive profits made possible by the absence of generic competition—Teva agreed to delay entering the market with generic ACTOS until August 17, 2012, and to delay entering the market with generic ACTO*plus* met until Mylan entered in 2012.

16. Defendants' unlawful schemes and Exclusion Payment Agreements were designed to and did in fact: (a) delay the entry of less expensive generic versions of ACTOS in the United States; (b) fix, raise, maintain, or stabilize the price of ACTOS and its generic equivalents; (c) permit Takeda to maintain a monopoly in the United States for ACTOS and its generic equivalents; (d) allocate 100% of the United States market for ACTOS and its generic equivalents to Takeda; (e) delay the entry of less expensive generic versions of ACTO*plus* met in the United States; and (f) fix, raise, maintain, or stabilize the price of ACTO*plus* met and its generic equivalents.

17. Plaintiffs bring this action as a class action on behalf of all consumers and third-party payors (collectively, "End-Payors") in certain States, the District of Columbia, and Puerto

Rico who indirectly purchased, paid and/or provided reimbursement for branded and/or generic ACTOS and/or ACTO*plus* met products, other than for re-sale, since January 17, 2011 with respect to ACTOS and since February 25, 2011 with respect to ACTO*plus* met (*see* Class Definitions below).

18. Plaintiffs assert claims for compensatory and/or treble damages for violations of the State laws enumerated below.

III. JURISDICTION AND VENUE

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

20. Defendants are subject to personal jurisdiction in this Court, including general and specific jurisdiction.

21. Defendants Takeda[1], Mylan, Actavis, Ranbaxy[2] and Teva have consented to the jurisdiction of this Court, as specifically set forth in their respective Exclusion Payment Agreements. *See* Termination of Litigation Agreements re Ranbaxy (¶7.5), Mylan (¶7.5), Watson (¶7.5) and Teva (¶8.5) ("The Parties agree that all actions arising out of or in connection

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[1] Excluding Defendant Takeda America Holdings, Inc., which is a wholly-owned subsidiary of Defendant Takeda Pharmaceutical Company Limited.

[2] Excluding Defendants Ranbaxy, Inc.which is both a wholly owned subsidiary of Defendant Ranbaxy Laboratories, Ltd. and is the United States parent corporation of Defendant Ranbaxy Pharmaceuticals, Inc.

with this Agreement, or related to any matter which is the subject of this Agreement, shall be subject to the exclusive jurisdiction of the United States District Court for the Southern District of New York, and consent to the personal jurisdiction of and venue in said court.").

22. This Court has general jurisdiction over each Defendant because one or more of the Defendants has engaged in such a continuous and systematic course of business in this District as to render it at home in New York, sufficient to satisfy both C.P.L.R. §301 and the requirements of due process. Such course of business includes, but is not limited to:

a. One or more of the Defendants has employees, offices and/or facilities in New York;

b. One or more of the Defendants actively solicits business in and derives substantial sales and revenue from New York;

c. One or more of the Defendants has substantial and ongoing business relationships with New York customers, employees and/or companies; and

d. One or more of the Defendants is registered with the New York State Department of State to do business in New York, as a so-called foreign corporation.

23. This Court has specific jurisdiction over each Defendant because one or more of the Defendants purposefully directed its unlawful anticompetitive activities in New York and this lawsuit results from injuries that arise out of and relate to those New York activities, sufficient to satisfy both C.P.L.R. §302 and the requirements of due process. Such New York activities include, but are not limited to the Exclusion Payment Agreements that are the subject matter of this action: (i) were negotiated, in part, here in New York, (ii) arose out of and resulted in the termination of underlying patent litigation that was pending here in this District; (iii) established that New York law governs their construction; and (iv) consented to the jurisdiction of this Court in connection with any action arising out of or in connection with these Agreements.

24. One or more of the Defendants sold the pharmaceutical products at issue in New York at supra-competitive prices, received substantial revenue from the sale of these products in New York and therefore reaped the benefits of its conduct from New York; and

25. One or more of the Defendants agreed to the jurisdiction of this Court in the underlying patent litigations.

26. Venue is appropriate in this district under 28 U.S.C. §1391(b) and (c) because Defendants transact business within this district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district.

IV. PARTIES

A. Plaintiffs

27. Plaintiff United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW Local 1776") is an employee health and welfare benefit plan with its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. Plaintiff UFCW Local 1776 indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Arizona, Florida, New Jersey, Ohio, Pennsylvania and Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

28. Plaintiff Crosby Tugs, LLC ("Crosby Tugs") is a Louisiana limited liability company with its principal place of business in Galliano, Louisiana. Plaintiff Crosby Tugs indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Louisiana, Maryland, Mississippi and Texas other than for resale, and purchased, paid and/or

provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

29. Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund ("IUOE Local 132") is an employee welfare benefit plan with its primary office in Huntington, West Virginia. Plaintiff IUEO Local 132 indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Florida, Illinois, North Carolina, Ohio, Pennsylvania, Texas and West Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

30. Plaintiff NECA-IBEW Welfare Trust Fund ("NECA-IBEW") is an employee welfare benefit plan with its primary office in Decatur, Illinois. Plaintiff NECA-IBEW indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Alabama, California, Florida, Illinois, Indiana, Kentucky, New Jersey, Nevada, Washington and Wisconsin other than for re-sale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Period, and has thereby been injured.

31. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Plaintiff Providence is a self-insured health and welfare plan. Plaintiff Providence indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Arizona, Connecticut, Florida, Hawaii, Illinois Maine, Massachusetts, Missouri, New Hampshire, New Jersey, New

York, North Carolina, Pennsylvania, Rhode Island Texas and Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

32. Painters District Council No. 30 Health & Welfare Fund ("Painters Fund") is an employee welfare benefit plan with its principal place of business in Aurora, Illinois. Plaintiff Painters Fund indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Florida, Illinois, Indiana and Pennsylvania other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

33. Plaintiff Minnesota and North Dakota Bricklayers and Allied Craftworkers Health Fund ("Bricklayers and Allied Craftworkers Fund") is an employee welfare benefit plan, with its principal place of business in Mendota Heights, Minnesota. Plaintiff Bricklayers and Allied Craftworkers Fund indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Arizona, Florida, Minnesota and Wisconsin other than for re-sale and purchased, paid and/or provided reimbursement for generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

34. Plaintiff New England Electrical Workers Benefits Fund ("NEEWBF") is an employee welfare benefit plan with its principal place of business in Wallingford, Connecticut. Plaintiff NEEWBF indirectly purchased, paid and/or provided reimbursement for ACTOS and/or ACTO*plus* met in California, Connecticut, Florida, Massachusetts, Maine, Mississippi,

Nebraska, New Hampshire, New Mexico, New York, North Carolina, South Carolina, Tennessee, Texas and Vermont other than for resale and purchased, paid and/or provided reimbursement for generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available, at supracompetitive prices during the Class Periods, and was thereby injured.

35. Plaintiff MAN-U Service Contract Trust Fund ("MAN-U") is a an employee health and welfare benefit plan trust with its principal place of business at 7130 Columbia Gateway Drive, Suite A, Columbia, MD 21046. Plaintiff MAN-U indirectly purchased and/or provided reimbursement for ACTOS and/or ACTO*plus* met in the District of Columbia, Florida, Illinois, Maryland, Pennsylvania and Virginia other than for re-sale and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available at supracompetitive prices, and has thereby been injured.

36. Plaintiff 199SEIU is an employee health and welfare benefit plan trust with its principal place of business in New York. Plaintiff 199SEIU indirectly purchased and/or provided reimbursement for ACTOS and/or ACTO*plus* met in Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Virginia, District of Columbia and Puerto Rico other than for re-sale and purchased, paid and/or provided reimbursement for the generic versions of ACTOS and/or ACTO*plus* met other than for re-sale once they became available at supracompetitive prices, and has thereby been injured.

B. Defendants

37. Defendant Takeda Pharmaceutical Company Limited is a Japanese company with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645.

38. Defendant Takeda America Holdings, Inc. is a wholly-owned subsidiary of Defendant Takeda Pharmaceutical Company Limited, and is the United States parent corporation of Defendants Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. Defendant Takeda America Holdings, Inc. is a corporation organized under the law of the State of New York with its principal place of business at 767 Third Avenue, New York, New York 10017.

39. Defendant Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

40. Defendant Takeda Development Center Americas, Inc., formerly known as Takeda Global Research and Development Center, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

41. The foregoing Defendants will collectively be referred to as "Takeda."

42. Defendant Mylan, Inc., formerly known as Mylan Laboratories, Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

43. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

44. The foregoing "Mylan" Defendants will together be referred to as "Mylan."

45. Defendant Actavis plc is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland, and its United States

place of business in Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group in or around October 2012. On or about October 1, 2013, Actavis, Inc. changed its name to Actavis plc.

46. Defendant Watson Laboratories, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc.

47. The foregoing "Actavis" Defendants will together be referred to as "Actavis."

48. Defendant Ranbaxy Laboratories, Ltd. is an international pharmaceutical company headquartered in Gurgaon, Haryana, India. Ranbaxy is a member of the Daiichi Sankyo Group, which is headquartered in Tokyo, Japan. Defendant Ranbaxy Laboratories, Ltd.'s principal place of business in the United States is at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

49. Defendant Ranbaxy, Inc. is a wholly-owned subsidiary of Defendant Ranbaxy Laboratories, Ltd. and is its North American commercial arm. Defendant Ranbaxy, Inc. also is the United States parent corporation of Defendant Ranbaxy Pharmaceuticals, Inc. Defendant Ranbaxy, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

50. Defendant Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Defendant Ranbaxy, Inc. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

51. The foregoing "Ranbaxy" Defendants will collectively be referred to as "Ranbaxy."

52. Defendant Teva Pharmaceutical Industries, Ltd., one of the largest pharmaceutical companies in the world, is headquartered in Petah Tikva, Israel.

53. Defendant Teva Pharmaceuticals USA, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

54. The foregoing "Teva" Defendants will together be referred to as "Teva."

55. All of Defendants' wrongful actions described in this Complaint are part of, and in furtherance of, the anticompetitive scheme and anticompetitive agreements (as further described below), and were authorized, ordered, and/or executed by Defendants' various officers, agents, employees, and/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 Defendants' actual, apparent, and/or ostensible authority.

V. INDUSTRY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs, Listing Patent Information in the Orange Book, and the Substitution of Generic Drugs for Brand Name Drugs

56. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301–392. An NDA must include specific data concerning

the safety and effectiveness of the drug, as well as information on any applicable patents. 21 U.S.C. § 355(a), (b).

57. When the FDA approves a branded drug manufacturer's NDA, the manufacturer may list in the Orange Book any patents the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug before the expiration of the listed patents. The branded drug manufacturer may also list in the Orange Book any patents issued after the FDA approved the NDA within thirty days of their issuance. 21 U.S.C. § 355(b)(1) & (c)(2).

58. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify a branded drug manufacturer's patents and patent information for accuracy or trustworthiness. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

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

"therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

60. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart. 21 U.S.C. § 355(j)(8)(B).

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

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

2. Requirements for Submitting Patent Information

63. The regulatory structure created by the Hatch-Waxman Act includes a process for identifying and addressing patents that arguably apply to brand and generic drug products. This regulatory structure requires the holder of an NDA to submit information concerning its patents

to the FDA, which incorporates the information into the Orange Book. Patent information is listed in the Orange Book for each NDA to which the patent may apply. Then, when a generic company seeks to file an ANDA, it must submit patent certifications or statements, described more fully below, to each patent listed in the Orange Book for the NDA that is the reference listed drug for the ANDA.

64. Under the Hatch-Waxman Act, the NDA holder must submit certain required information concerning "any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

65. When Takeda submitted patent information regarding the '584 Patent and '404 Patent for ACTOS—in 1999 and 2002, respectively—the relevant statute required the NDA applicant to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C.A. § 355(b)(1) (1999) & (2002).

66. The then-applicable regulations identified three types of patents that could properly be listed: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." 21 C.F.R. § 314.53(b) (1999) & (2002). The regulations further provided that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product." *Id.* (emphasis added). The NDA holder also could properly list a

patent for a drug product only "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale *of the drug product*." *Id.* (emphasis added). In short, for patents that claimed a drug product, the NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the drug product that was the subject of the NDA; the patent's drug product claim could claim not just *some* drug product—it had to claim the *relevant* drug product, *i.e.*, the FDA approved drug product as to which the NDA applicant listed the patent.

67. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use." 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002). The FDA expressly refused to police the proper listing of patents and patent information, noting that it "does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA," and that it "believes that the declaration requirements under § 314.53(c) [requiring the applicant to declare "that Patent No. ____ covers the formulation, composition, and/or method of use of (name of drug product)"], as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted." *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994).

68. Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug product claims, and patents described as containing only method-of-use claims. If the patentee describes the patent in the patent information as containing a relevant drug product claim, an ANDA applicant desiring to market its generic product before the patent expires must file a Paragraph IV Certification, certifying

that the patent is invalid, unenforceable, or would not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). The patentee and/or NDA holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant. In addition, and of particular importance here, the FDA is prohibited from approving a subsequent applicant's ANDA until 180 days after the first-filer has entered the market. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity creates a "bottleneck" that delays *all* generic competition until 180 days after the first-filer enters the market.

69. By contrast, if the patentee describes the patent as containing only relevant method-of-use claims, in certain circumstances an ANDA applicant can submit what is known as a "Section viii Statement." 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii). In a Section viii Statement, the ANDA applicant states that it is not seeking approval for the particular use covered by the method-of-use patent. If an ANDA applicant makes only a Section viii Statement, then the patentee or NDA holder *cannot* obtain an automatic 30-month stay on generic competition even if it sues the ANDA applicant for patent infringement. And the FDA can approve an ANDA containing only a Section viii Statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

70. Whether a patent actually claims the relevant drug product is irrelevant for purposes of Paragraph IV certifications. Rather, FDA regulations and instructions made unmistakably clear that the *patent information* submitted by the NDA applicant determined whether generic manufacturers would be permitted to make Paragraph IV certifications and thus would be eligible for the 180-day exclusivity period. *See*, for example, FDA Proposed Rule, *Abbreviated New Drug Application Regulations*, 54 FR 28872, at 28885 (July 10, 1989) ("the

patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification"); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a Section viii statement is based on "patent information ... submitted under ... § 319.53").

71. In short, describing a patent as containing a relevant drug product claim gives the patentee two key competitive advantages---an automatic 30-month stay on generic competition, and a bottleneck that delays all generic competition until 180 days after the first generic filer enters the market.

3. Paragraph IV Certifications

72. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

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

ii. that the patent for the branded drug has expired (a "Paragraph II certification");

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

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

73. If a generic drug manufacturer files a Paragraph IV Certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to

the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic drug manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

74. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a Paragraph IV Certification typically receives a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV Certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug is the only available generic drug for at least six months.

75. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV Certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—is

demonstrated by the fact that generic drug manufacturers have prevailed in Paragraph IV Litigation in cases involving 73% of the drug products studied—either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

76. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicant could help a branded drug manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic drug manufacturers. In exchange for payments from the branded drug manufacturer, the first generic drug manufacturer applicant could agree to delay marketing its generic drug, thereby extending the 180-day exclusivity bottleneck.

77. On December 8, 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to make it more difficult for branded drug and generic drug manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic drug products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

78. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV Certification), at least one of the following has occurred: (i) a final

decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

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

B. The Benefits of Generic Drugs

80. Generic versions of branded drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. The only material difference between generic drugs and branded drugs is their price: generic drugs are usually at least 25% less expensive than their branded drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug manufacturer competitors in the market for a given branded drug. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The

Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, competition from generic drugs is viewed by branded drug manufacturers, such as Takeda, as a grave threat to their bottom lines.

81. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

82. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower copays for generic drugs in order to encourage their use.

83. Generic drug competition enables all putative Class members to (i) purchase generic versions of a drug at substantially lower prices; and/or (ii) purchase a branded drug at a reduced price.

84. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the branded drug, and, therefore, the branded drug manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, such as Takeda, which are well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the introduction of generic drug competition into the market, including through tactics such as the improper patent listing and Exclusion Payment Agreements.

C. The Impact of Authorized Generics

85. The 180-day marketing exclusivity to which first-filer generic drug manufacturers may be entitled does not prevent a branded drug manufacturer from marketing its own generic drug alternative to the branded drug during the 180-day period. Such an "authorized generic" is chemically identical to the branded drug, but is sold as a generic drug through either the branded manufacturer's subsidiary (if it has one) or through a third-party generic drug manufacturer. Competition from an authorized generic drug during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

86. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generic drugs capture a significant portion of sales, reducing the first-filer generic drug manufacturer's revenues by approximately half on average during the 180-day exclusivity period. The first-filing generic drug manufacturer makes significantly less money when it faces competition from an authorized generic because (i) the authorized generic drug takes a large share of unit sales away from the first filer; and (ii) the presence of an additional generic drug in the market causes prices to decrease.

87. Although first-filing generic drug manufacturers make significantly less money when they must compete with an authorized generic drug during the first 180 days, consumers and other drug purchasers, such as Plaintiffs and members of the putative End-Payor Classes, benefit from the lower prices caused by competition between the authorized generic drug manufacturer and the first-filing generic drug manufacturer.

88. Given the significant negative impact of an authorized generic drug manufacturer on the first-filing generic drug manufacturer's revenues, a branded drug manufacturer's agreement not to launch an authorized generic drug has tremendous monetary value to the generic drug manufacturer. Branded drug manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as Plaintiffs and members of the putative End-Payor Classes, of the lower prices resulting from two forms of competition: (i) between the branded drug and the generic drug; and (ii) between the generic drugs.

VI. DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. Takeda Submits False and Misleading Information Regarding the '584 Patent and '404 Patent.

89. On January 15, 1999, Takeda submitted to the FDA NDA 21-073, seeking approval to manufacture, market, and sell ACTOS, which contains the active ingredient pioglitazone hydrochloride, and is used to improve glycemic control in adults with Type 2 diabetes when diet and exercise are not sufficient. On July 15, 1999, the FDA approved Takeda's NDA for the use of ACTOS to improve glycemic control in adults with Type 2 diabetes—either as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

90. Pursuant to the FDA's requirements, Takeda submitted the '777 Patent, entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents," for listing in the Orange Book as a drug substance patent covering ACTOS. The '777 Patent claims the active ingredient for ACTOS, pioglitazone hydrochloride, and was issued to inventors Kanji Meguro and Takeshi Fujita on August 18, 1987, and assigned to Takeda. The '777 Patent purports to claim the novel compound commonly known under the nonproprietary name "pioglitazone" and its pharmacologically acceptable salts. ACTOS and ACTO*plus* met are both covered by the '777 Patent, which expired on January 17, 2011.

91. As stated previously, Takeda knew its blockbuster drug would suffer from generic competition upon expiration of the '777 Patent. In order to extend its patent monopoly beyond January 17, 2011, Takeda knowingly and falsely represented to the FDA that the '584 and '404 patents are something they are not—drug product patents that claim the ACTOS drug product.

92. The '584 Patent, entitled "Pharmaceutical Composition," purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* a biguanide (*e.g.*, metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide (*e.g.*, metformin). Takeda is the owner, by assignment, of the '584 Patent, which expires on June 19, 2016. Takeda knew that the '584 patent did not claim the ACTOS drug product, but only a method of using it. ACTO*plus* met, not ACTOS, is the purported commercial embodiment of the '584 Patent. Nevertheless, Takeda submitted patent information to the FDA describing the '584 Patent as a drug product patent *that claims ACTOS*. When submitting the '584 Patent information to the FDA, Takeda knew that the information was false and misleading, and Takeda acted with the purpose and effect of impairing competition from generic drugs.

93. The '404 Patent, entitled "Pharmaceutical Composition," purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer. Takeda is the owner, by assignment, of the '404 Patent, which expires on June 19, 2016. Takeda knew that the '404 patent did not claim the ACTOS drug product, but only a method of using it. Duetact, not ACTOS, is the purported commercial embodiment of the '404 Patent. Nevertheless, Takeda submitted patent information to the FDA describing the '404 Patent as a drug product patent *that claims ACTOS*. When submitting the '404 Patent information to the FDA, Takeda knew that the information was false and misleading, and Takeda acted with the purpose and effect of impairing competition from generic drugs.

94. In addition to the '777 Patent, the '584 Patent, and the '404 Patent, Takeda submitted eight other patents to the FDA for listing in the Orange Book. These patents (the "Method-of-Use Patents") claimed various methods of using ACTOS in combination with other drug products (such as biguanide or an insulin secretion enhancer) to treat various conditions or to reduce various side effects. Takeda listed the Method-of-Use Patents in the Orange Book as method of use patents, not drug substance or drug product patents.

95. Under both the Hatch-Waxman Act and the FDA's implementing regulations, the drug product claims of the '584 Patent and the '404 Patent do not form a permissible basis for Takeda to submit patent information describing the patents as drug product patents covering ACTOS.

96. *First*, Takeda could properly identify the '584 Patent and the '404 Patent as drug product patents claiming ACTOS only if the patents in fact claimed the ACTOS drug product. The patents unequivocally do not do so. The *only* active ingredient in ACTOS is pioglitazone hydrochloride. By contrast, the drug product claims in the '584 Patent and the '404 Patent claim drug products containing *both* pioglitazone *and* certain additional active ingredients—biguanide or an insulin secretion enhancer, respectively. Neither patent claims a drug product that contains pioglitazone as its sole active ingredient. Thus, the patents do not claim the ACTOS drug product as a matter of law.

97. *Second*, Takeda could not reasonably assert the drug product claims of the '584 Patent or the '404 Patent against generic drug manufacturers seeking to market ACTOS. The patents claimed only drugs *other* than the ACTOS drug product. In fact, it would be impossible for any ANDA referencing the ACTOS NDA to get FDA approval of a drug containing either of the compositions claimed in the '584 and '404 patents. Moreover, as noted in further detail below, although Takeda originally asserted those drug product claims against generic drug manufacturers of ACTOS, Takeda withdrew the claims before a court could rule on them—but only after the generic drug manufacturers had made their paragraph IV certifications against those two patents.

98. Nevertheless, on or about November 5, 1999, Takeda submitted patent information stating that the '584 Patent claimed both the "drug product" ACTOS and its "method of use." Similarly, on or about January 3, 2002, Takeda submitted patent information stating that the '404 Patent claimed both the "Drug Product" ACTOS and its "Method of Use." Takeda submitted the patent information knowing that it was false and misleading, and Takeda submitted that information with the purpose and effect of impairing competition from generic drugs.

99. In response to a Citizens Petition submitted to the FDA by another generic drug manufacturer, Defendant Teva asserted that Takeda had improperly caused the FDA to list the '584 Patent and '404 Patent in the Orange Book as drug product patents for ACTOS. In its Comment to the Citizens Petition, dated January 22, 2010, Takeda "confirm[ed] for FDA the listing of [the '584 Patent and '404 Patent] under the terms described in Takeda's original patent submissions." Takeda further acknowledged that it "characterized them for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to ACTOS under the original declarations...."

100. In a ruling on the Citizens Petition, dated March 15, 2010, the FDA confirmed that Takeda's original patent information had indeed "stated that the patents claimed both the drug product and a method of use." The FDA further concluded that "[i]n keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA." The FDA specifically noted that Takeda's January 22, 2010 Comment to the Citizens Petition had "reconfirm[ed]" the original listing. Moreover, "FDA's role in listing patents and patent information in the Orange Book is ministerial," and "FDA relies on the NDA sponsors to provide an accurate patent submission."

101. The FDA concluded that, because Takeda had submitted patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, all ANDA filers seeking approval to market generic ACTOS before the expiration of the patents were required to submit Paragraph IV Certifications, rather than Section viii Statements, with respect to them. The requirement that Teva and all ANDA filers submit Paragraph IV Certification -

and thereby become subject to the first-filer's 180-exclusivity – resulted from Takeda's description of the '584 Patent and '404 Patent as drug product patents claiming ACTOS: the FDA concluded that, "[I]t is the patent declaration submitted by the NDA holder and any subsequent amendments or supplements to that declaration that controls FDA's listing of patents and patent information. In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA."

102. But for Takeda's knowing submission of false and misleading patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, and its subsequent reaffirmation of the patent information in its January 22, 2010 Comment to the Citizens Petition, no ANDA filer would (or could) have submitted a Paragraph IV Certification for ACTOS with respect to the '584 Patent and '404 Patent. Consequently, no ANDA filer would have been entitled to claim the 180-day exclusivity with respect to generic ACTOS.

103. Absent a claim to the 180-day exclusivity, the incentive of the generic drug manufacturers that filed the first ANDAs for generic ACTOS—Defendants Mylan, Ranbaxy, and Actavis—would have been to enter the market as soon as the '777 Patent expired on January 17, 2011. Moreover, absent the first-filers' claim to the 180-day exclusivity—a claim that existed because Takeda improperly submitted patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product—many more additional generic drug manufacturers would have also entered the market on or about January 17, 2011, because they would not have been subject to any 180-day exclusivity.

104. In short, absent Takeda's submission of patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, massive generic entry, by ten or

more manufacturers of generic ACTOS, would have occurred on or about January 17, 2011. Entry by this number of generic drug manufacturers would have quickly driven the price of ACTOS and its generic equivalents down to near marginal cost, delivering more than $2 billion in cost savings to American consumers.

B. Takeda Delays the Entry of Generic ACTOS.

1. Takeda Files Paragraph IV Litigation Against Mylan, Ranbaxy, and Actavis

105. Generic drug manufacturers were eager to apply for FDA approval to market generic versions of ACTOS. On July 15, 2003, three generic manufacturers, Mylan, Ranbaxy, and Actavis, each filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTOS. (Alphapharm was also a first ANDA filer for generic ACTOS, but Mylan acquired Alphapharm before generic ACTOS was launched). The FDA ultimately concluded that Mylan, Ranbaxy, and Actavis were entitled to "shared" 180-day exclusivity with respect to generic ACTOS.

106. On or about September 8, 2003, Mylan notified Takeda that Mylan had filed ANDA No. 76-801 seeking to manufacture, market, and sell a generic version of ACTOS. As relevant here, Mylan's notice letter included a Paragraph IV Certification as to the '584 Patent and '404 Patent, and Section viii Statements as to the Method-of-Use Patents.

107. On September 9, 2003, Actavis notified Takeda that Actavis had filed ANDA No. 76-798 seeking to manufacture, market, and sell a generic version of ACTOS. As relevant here, Actavis' notice letter contained a Paragraph IV Certification as to the '584 Patent and '404 Patent, and Section viii Statements as to the Method-of-Use Patents.

108. On September 18, 2003, Ranbaxy notified Takeda that Ranbaxy had filed ANDA No. 76-800 seeking to manufacture, market, and sell a generic version of ACTOS. As relevant

here, Ranbaxy's notice letter contained a Paragraph IV Certification as to the '584 Patent and '404 Patent, and Section viii Statements as to the Method-of-Use Patents.

109. On October 17, 2003, Takeda filed three separate suits in the United States District Court for the Southern District of New York. As relevant here, Takeda alleged that Mylan's, Ranbaxy's, and Actavis' generic ACTOS products would infringe the drug product claims of the '584 Patent and '404 Patent, pursuant to 35 USC § 271(e)(2)(a), and induce infringement of the method-of-use claims of the '584 Patent and '404 Patent and certain of the Method-of-Use Patents, pursuant to 35 USC § 271(b). Takeda filed the patent infringement cases against Mylan, Actavis, and Ranbaxy without regard to the merits of the cases. During the litigation, Mylan, Actavis, and Ranbaxy secured substantial evidence via discovery supporting a host of defenses focusing on the: (i) enforceability of the '584 Patent and '404 Patent; (ii) validity of the '584 Patent and '404 Patent; and (iii) strength of Takeda's infringement allegations regarding the Patents and the Method-of-Use Patents. Indeed, before trial, Takeda withdrew its allegations that Mylan, Actavis, and Ranbaxy's generic ACTOS products infringed the drug product claims of the '584 Patent and '404 Patent.

110. In view of the looming expiration of the '777 Patent in January 2011, the district court set a trial date for April 2010 (subsequently moved to June 2010) to determine whether these Generic Defendants' generic ACTOS products would infringe the '584 Patent or '404 Patent and/or induce infringement of the '584 Patent, '404 Patent, and/or the Method-of-Use Patents.

111. To prevent generic entry using just the strength of its patents, Takeda would have had to defeat each of Mylan's, Ranbaxy's, and Actavis' arguments regarding direct and indirect infringement. Takeda instead decided to protect its monopoly by paying Mylan, Ranbaxy, and

Actavis to withdraw their defenses to the patents and delay introducing their generic ACTOS products.

2. Takeda and Mylan, Ranbaxy, and Actavis Execute Exclusion Payment Agreements to Delay Generic ACTOS.

112. On or about March 15, 2010, Takeda entered into an Exclusion Payment Agreement with each of Mylan, Actavis, and Ranbaxy. The Exclusion Payment Agreements required Takeda to immediately dismiss its patent infringement litigation against Mylan, Actavis, and Ranbaxy, and for the Generic Defendants to, in turn, drop their challenges to the Takeda patents. In addition, Mylan, Ranbaxy, and Actavis also agreed to delay launching their generic ACTOS products until August 17, 2012, or earlier under certain circumstances.

113. As the *quid pro quo* for Mylan's, Actavis' and Ranbaxy's agreements to drop their challenges to the patents and delay entry, Takeda agreed to pay Mylan, Ranbaxy, and Actavis substantial sums. Takeda's payments to the Generic Defendants under the Exclusion Payment Agreements took several forms.

114. *First*, Takeda agreed that in the event any other generic ACTOS entered the market before August 17, 2012, the licensed entry dates for Mylan, Ranbaxy, and Actavis would be moved up correspondingly. As discussed in further detail below, the purpose and effect of these acceleration clauses was to deter any other generic drug manufacturer from entering the market before then. Takeda, Mylan, Ranbaxy, and Actavis specifically intended these clauses to deter Teva from undermining the anticompetitive Exclusion Payment Agreements. Eliminating the potential for Teva to enter the market before Mylan, Ranbaxy, and Actavis (all as described more fully below) was of enormous benefit to the Generic Defendants – worth hundreds of millions of dollars – and was compensation that they could not have obtained even if they had

won the ACTOS patent litigation. The acceleration clauses were large and unjustified payments from Takeda to each of Mylan, Ranbaxy, and Actavis.

115. *Second*, Takeda agreed to give Ranbaxy a "sweetheart deal" on another product. Ranbaxy had not filed an ANDA seeking FDA approval to market ACTO*plus* met and had not made any certifications that Takeda's patents on ACTO*plus* met were invalid or would not be infringed by a generic version of ACTO*plus* met. In order to induce Ranbaxy to delay entry with its generic ACTOS, [redacted] was of substantial value to Ranbaxy and was compensation that it could not have been obtained even if it had won the ACTOS patent litigation. [redacted] was a large and unjustified payment from Takeda to Ranbaxy.

116. *Third*, Takeda agreed to give Actavis a "sweetheart deal" on another product. [redacted]. In order to induce Actavis to delay entry with its generic ACTOS, [redacted] was of substantial value to Actavis and was compensation that it could hot have obtained even if it had won the ACTOS patent litigation. [redacted] was a large and unjustified payment from Takeda to Actavis.

117. All of these benefits had substantial value to Mylan, Ranbaxy, and Actavis, and are compensation that they could not have otherwise obtained even if they had litigated and won

the patent cases. These payments caused Mylan, Ranbaxy, and Actavis to stay out of the market longer than they otherwise would have. And Takeda made these payments to Mylan, Ranbaxy, and Actavis in exchange for their agreeing to delay entry with their generic ACTOS products. In short, Takeda made large, unjustified payments to Mylan, Ranbaxy, and Actavis to delay their entry into the market with generic ACTOS.

3. The Bottleneck Delays Other Potential Generic Competitors.

118. Mylan, Ranbaxy, and Actavis filed their ANDAs for ACTOS before enactment of the 2003 MMA amendments. Under the law before the amendments, the first generic manufacturer(s) to file an ANDA with a Paragraph IV Certification could not forfeit the 180-day exclusivity by failing to market the drug. Therefore, the first generic drug manufacturer applicant could agree with the branded drug manufacturer to delay marketing the generic, while still safely retaining the 180-day exclusivity. By thus "parking" its 180-day exclusivity, the first filer could create a "bottleneck" that precluded *all* generic drug manufacturers from entering the market until 180 days after the first filer entered. The intended effect of Takeda's Exclusion Payment Agreements with each of Mylan, Ranbaxy, and Actavis was to delay entry into the market by them and all subsequent ANDA filers.

119. At least seven other generic drug manufacturer competitors notified Takeda they had filed ANDAs seeking to market a generic version of ACTOS. Many of these competitors sent to Takeda notice letters, including a Paragraph IV Certification, with respect to the '584 Patent and '404 Patent.

120. Takeda filed multiple patent infringement suits alleging that these manufacturers' generic ACTOS products would directly infringe the '584 Patent and '404 Patent, and indirectly infringe the Method-of-Use Patents.

121. Takeda filed the patent infringement cases against these potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing the cases, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

122. In light of the bottleneck created by Takeda's Exclusion Payment Agreements with Mylan, Ranbaxy, and Actavis, beginning in 2010, all of the subsequent ANDA filers entered into joint stipulations of dismissal of their patent cases with Takeda. All of these potential competitors agreed to delay entry into the market until 180 days after Mylan, Ranbaxy, and Actavis entered. Absent the bottleneck created by Takeda's improper listing of patent information with respect to the '584 Patent and '404 Patent and Takeda's subsequent execution of Exclusion Payment Agreements with Mylan, Ranbaxy, and Actavis, many or most of these later ANDA filers would have entered the market much sooner than they did.

C. Takeda Delays the Entry of Generic ACTO*plus* met.

1. Takeda Files Paragraph IV Litigation Against Mylan.

123. On October 27, 2004, Takeda submitted NDA 21-842, seeking FDA approval to manufacture, market, and sell a fixed single dose combination of pioglitazone hydrochloride and metformin hydrochloride designed to improve glycemic control in adults with Type 2 diabetes, which Takeda subsequently marketed as ACTO*plus* met. Takeda listed the '584 Patent in the Orange Book as a drug product patent for ACTO*plus* met, and listed several additional patents as applicable method-of-use patents. The FDA approved Takeda's NDA for ACTO*plus* met on August 29, 2005.

124. ACTO*plus* met quickly grew to become one of Takeda's most profitable drugs, delivering more than $413 million in annual sales by 2012.

125. On or about June 23, 2008, Mylan notified Takeda that Mylan had filed ANDA No. 90-406, seeking to manufacture, market, and sell a generic version of ACTO*plus* met. Mylan's notice letter included a Paragraph IV Certification with respect to the '584 Patent and certain method-of-use patents. Mylan was the first ANDA filer to submit a substantially complete ANDA with a Paragraph IV Certification to market generic ACTO*plus* met.

126. On August 5, 2008, Takeda filed suit in the United States District Court for the Southern District of New York, alleging that Mylan's ANDA for generic ACTO*plus* met directly infringed, and would induce infringement of, the '584 Patent and the method-of-use patents.

127. Takeda filed the patent infringement case against Mylan without regard to the merits of the case. Simply by filing the lawsuit, Takeda obtained the automatic exclusion of Mylan from the market for thirty months and the ability to create a 180-day exclusivity bottleneck.

128. During the litigation, Mylan conducted discovery supporting a host of defenses focusing on the: (i) enforceability of the '584 Patent and the method-of-use patents: (ii) validity of the '584 Patent and the method-of-use patents: and (iii) strength of Takeda's indirect and contributory patent infringement allegations.

129. To prevent generic entry using just the strength of its patents, Takeda would have had to defeat Mylan's arguments regarding direct and indirect infringement. Takeda instead decided to protect its supracompetitive profits by paying Mylan to withdraw its defenses to the patents and delay introducing generic ACTO*plus* met.

2. Takeda And Mylan Enter Into an Exclusion Payment Agreement to Delay Generic ACTO*plus* met.

130. On or about March 15, 2010, Takeda entered into an Exclusion Payment Agreement with Mylan. Under the terms of the Exclusion Payment Agreement, Mylan agreed to

drop its challenge to Takeda's patents. Mylan also agreed to stay out of the market with generic ACTO*plus* met until December 14, 2012, or August 17, 2012 if Takeda's sales of ACTO*plus* met dipped below a certain threshold (which they did).

131. As the *quid pro quo* for Mylan's agreement to drop its challenges to Takeda's patents and delay entry of generic ACTO*plus* met, Takeda agreed to pay Mylan substantial sums. Takeda's payments to Mylan under the Exclusion Payment Agreement took several forms.

132. *First*, Takeda agreed that, in the event that any other generic ACTO*plus* met entered the market before the time specified for Mylan to enter, the licensed entry date for Mylan would be moved up correspondingly. As discussed in further detail below, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Mylan's scheduled entry date.

133. *Second,* Takeda agreed to provide to Mylan the payments with respect to ACTOS discussed in detail above. As noted in detail below, the payments and provisions were designed to, and did in fact, deter Teva from undermining the Exclusion Payment Agreement that Takeda and Mylan reached with respect to ACTOS. The terms on which Takeda and Mylan agreed to settle the ACTOS lawsuit were contingent on the terms on which those parties agreed to settle the ACTO*plus* met lawsuit, and *vice versa*. In exchange for all of the payments that Mylan received with respect to both lawsuits, including those successfully designed to deter Teva from undermining the ACTOS anticompetitive scheme, Mylan agreed to delay entry with ACTO*plus* met.

134. All of these benefits had substantial value to Mylan, and are compensation that it could not have otherwise obtained even if it had litigated and won the ACTO*plus* met patent case. These payments caused Mylan to stay out of the market with ACTO*plus* met longer than it

otherwise would have done. And Takeda made these payments to Mylan in exchange for its agreeing to delay entry with its generic ACTO*plus* met product. In short, Takeda made large, unjustified payments to Mylan to delay entry into the market with generic ACTO*plus* met.

3. The Bottleneck Delays Entry by Other Potential Generic Competitors.

135. As the first ANDA filer to submit a substantially complete ANDA with a Paragraph IV Certification with respect to ACTO*plus* met, Mylan secured the Hatch-Waxman 180-day exclusivity. Although Congress had sought in the 2003 MMA amendments to reduce the incidence of drug manufacturers entering into Exclusion Payment Agreements to create "bottlenecks," unscrupulous manufacturers could still structure such agreements to create very substantial obstacles to entry by later-filing generics. As noted in detail above, under the MMA, the generic first-filer retains its 180-day exclusivity if it enters into a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV Certification were invalid or not infringed. In order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are then forced to obtain a judgment that all patents for which the first filing generic manufacturer filed Paragraph IV Certifications are invalid or not infringed.

136. Takeda and Mylan in fact "gamed the system" in just this way, entering into a voluntary dismissal without the requisite findings that would have resulted in a forfeiture of Mylan's 180-day exclusivity. Consequently, the Takeda/Mylan Exclusion Payment Agreement constructed very substantial barriers to entry by later-filing generic drug manufacturers.

137. At least four other generic drug manufacturer competitors notified Takeda that they had filed ANDAs seeking to manufacture, market and sell a generic version of ACTO*plus*

met. Each of these notice letters included a Paragraph IV Certification with respect to the '584 Patent and the method-of-use patents.

138. Takeda filed multiple patent infringement suits alleging the generic ACTO*plus* met products would directly infringe the '584 Patent and indirectly infringe the method-of-use patents. Takeda filed these patent infringement cases against the potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing the lawsuits, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

139. In light of the bottleneck created by Takeda's Exclusion Payment Agreement with Mylan, beginning in April 2010, all of these subsequent ANDA filers entered into joint stipulations dismissing their patent cases with Takeda. All of these potential competitors agreed to delay entry into the market until 180 days after Mylan entered. Absent the bottleneck created by Takeda's Exclusion Payment Agreement with Mylan, many or most of these later ANDA filers would have entered the market much sooner than they did.

D. Defendants Neutralize the Threat Teva Posed to Unravel the Anticompetitive Agreements.

1. Teva Files Only Section viii Statements as to ACTOS.

140. With the execution of the Exclusion Payment Agreements for both ACTOS and ACTO*plus* met in March 2010, and the consequent bottlenecks that also delayed entry by later-filing generic drug manufacturers, Takeda and its generic co-conspirators—Mylan, Ranbaxy, and Actavis—had tamed almost all of the threats that could unleash competitive rivalry and bring lower prices to consumers before the dates specified in the Exclusion Payment Agreements. But one significant threat remained, so Takeda and its generic coconspirators worked together to neutralize the potential competitor and bring it into the conspirators' non-competition pact.

141. On or around July 14, 2004, Teva filed ANDA No. 77-210, seeking to manufacture, market and sell generic versions of ACTOS. Teva refused, however, to submit Paragraph IV Certifications with respect to the '584 Patent and '404 Patent. Instead, with respect to those patents as well as the Method-of-Use Patents, Teva included only Section viii Statements. As permitted by applicable regulations, the Section viii Statements asserted that Teva's label for its generic ACTOS would "carve out" information regarding methods of using ACTOS in combination with a biguanide or an insulin secretion enhancer (the methods of use claimed by the '584 Patent and '404 Patent, respectively) or other uses covered by the Method-of-Use Patents.

142. As noted in detail above, Teva's decision not to include Paragraph IV Certifications with respect to the '584 Patent and '404 Patent raised the possibility that the FDA could approve Teva's ANDA without regard to whether any other ANDA applicant was otherwise entitled to a 180-day exclusivity period with respect to ACTOS. Thus, it was possible for Teva to leap ahead of Mylan, Ranbaxy, and Actavis and launch a generic version of ACTOS once the '777 Patent expired in January 2011. Takeda did not sue Teva with respect to its ANDA for ACTOS at that time, instead waiting to sue until Teva also sought approval to sell ACTO*plus* met.

143. On April 14, 2009, Teva notified Takeda that Teva had filed ANDA No. 91-155, seeking to manufacture, market and sell generic versions of ACTO*plus* met. Teva's notice letter included a Paragraph IV Certification that the '584 Patent and two additional Takeda patents were invalid and/or not infringed.

144. On or about May 18, 2009, Takeda filed suit against Teva in the United States District Court for the Southern District of New York. Takeda alleged that Teva directly

infringed, intentionally induced infringement, and/or contributed to the infringement of the patents as to which Teva had submitted Paragraph IV Certifications. In addition to these allegations regarding ACTO*plus* met, Takeda also alleged that Teva's ANDA for ACTOS intentionally induced infringement of the '584 Patent, '404 Patent, and the Method-of-Use Patents. Takeda filed the lawsuit without regard to its merits.

145. The lawsuit was scheduled for trial beginning in June 2010, in time for Teva to obtain a favorable ruling before the expiration of the ACTOS '777 Patent in January 2011.

146. On March 15, 2010, while the lawsuit was pending, the FDA issued its decision on the Citizens Petition discussed in detail above, concluding that, in its purely ministerial role, the FDA would rely solely on Takeda's patent information. Because Takeda submitted patent information stating that the '584 Patent and '404 Patent claimed both the "drug product" ACTOS and its "method of use," the FDA concluded that it could not approve any ANDA that did not include a Paragraph IV Certification as to the '584 Patent and '404 Patent, which Teva's ANDA for ACTOS did not include.

147. On March 30, 2010, Teva countered this development by filing a motion to amend its answer to add a counterclaim that Takeda had improperly submitted patent information for the '584 Patent and '404 Patent describing the patents as drug product patents claiming ACTOS. Had Teva succeeded on its counterclaim, Teva would not have been subject to the 180-day bottleneck that Takeda and Mylan, Ranbaxy, and Actavis constructed and extended with their Exclusion Payment Agreements, and Teva could have entered the market with generic ACTOS as early as January 17, 2011.

148. Shortly after Teva filed its motion regarding Takeda's improper listing of patent information for the '584 Patent and '404 Patent, Takeda and Teva began serious settlement

negotiations. At the parties' joint request, on April 14, 2010, the court adjourned the June 2010 trial date.

149. During the settlement negotiations, Takeda used "carrots and sticks." The sticks included the acceleration clauses that Takeda and its other generic drug manufacturer co-conspirators had incorporated in the Exclusion Payment Agreements for both ACTOS and ACTO*plus* met. As noted above, the acceleration clauses in Takeda's Exclusion Payment Agreement with each of Mylan, Ranbaxy, and Actavis provided that, in the event that any other manufacturer succeeded in entering the market with a generic ACTOS product before August 17, 2012, the licensed entry date for Mylan, Ranbaxy, and Actavis would be accelerated to the earlier date. The acceleration clauses thus ensured that no other generic drug manufacturer, no matter how much time and resources it spent in its litigation against Takeda, and no matter how successful the generic drug manufacturer was in the litigation, could enter the market before Mylan, Ranbaxy, and Actavis. The Exclusion Payment Agreement between Takeda and Mylan with respect to ACTO*plus* met had a similar acceleration clause.

150. The purpose and effect of the acceleration clauses was to dramatically reduce Teva's incentive to try to enter the market before Mylan, Ranbaxy, and Actavis. Absent the acceleration clauses, Teva had a significant possibility of entering the market with generic ACTOS before August 17, 2012, thereby enjoying a substantial period with the only generic ACTOS product on the market. By eliminating this possibility, the acceleration clauses resulted in later generic entry in at least two ways: (i) the clauses directly reduced Teva's incentive to continue litigating in order to gain entry before Mylan, Ranbaxy, and Actavis, and (ii) by eliminating the threat to Mylan's, Ranbaxy's, and Actavis' 180-day exclusivity, the clauses compensated them for delaying their entry into the market. In short, the acceleration clauses

eliminated Teva's competitive threat to Mylan, Ranbaxy, and Actavis, in return for which they agreed to later entry.

151. While keeping most of the terms in their Exclusion Payment Agreements confidential, Mylan, Ranbaxy, and Actavis agreed that Takeda could advise Teva of the existence of the acceleration clauses. The purpose and effect of the disclosure was to dissuade Teva from entering the market before August 17, 2012.

152. The "carrots" that Takeda offered to Teva to give up the patent fight were the payments that the parties included in their unlawful Exclusion Payment Agreement, discussed below.

2. Takeda and Teva Execute an Exclusion Payment Agreement to Delay Generic ACTOS and Generic ACTO*plus* met.

153. On December 22, 2010, Takeda and Teva entered into an Exclusion Payment Agreement pursuant to which Teva agreed to: (i) drop its challenges to Takeda's patents with respect to both ACTOS and ACTO*plus* met; (ii) drop its proposed counterclaim asserting that Takeda had submitted false and misleading patent information as to the '584 Patent and '404 Patent; and (iii) stay out of the market with generic ACTOS until August 17, 2012, and stay out of the market with generic ACTO*plus* met until the date on which Mylan entered the market.

154. As the *quid pro quo* for Teva's agreement to significantly delay competition, Takeda agreed to pay Teva substantial compensation. Takeda's payments to Teva under the Exclusion Payment Agreement took at least the following forms.

155. *First*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of ACTOS during Teva's first 180 days of marketing. This non-competition pledge provided substantial compensation to Teva, which could expect higher unit sales, at a

higher price, absent Takeda's authorized generic version of ACTOS in the market. The non-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

156. *Second*, Takeda agreed that, with the exception of the licenses to which it had already agreed with Mylan, Ranbaxy, and Actavis, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic ACTOS until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

157. *Third*, Takeda agreed that, in the event any other generic ACTOS entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

158. *Fourth*, Takeda granted Teva a license to market generic ACTO*plus* met under Takeda's NDA beginning on the date that Mylan first entered the market with its generic ACTO*plus* met. Anticipating that they would succeed in enticing Teva to join the non-competition pact, Takeda and Mylan had agreed that Takeda could provide such a license to Teva with respect to ACTO*plus* met, and Takeda and Mylan had included [redacted].

159. *Fifth*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of ACTO*plus* met during Teva's first 180 days of marketing. This provided substantial compensation to Teva, which could expect higher unit sales, at a higher price, absent Takeda's authorized generic version of ACTO*plus* met in the market. The no-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

160. *Sixth*, Takeda agreed that, with the exception of the licenses already granted to Mylan, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic ACTO*plus* met until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

161. *Seventh*, Takeda agreed that, in the event any other generic ACTO*plus* met entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

162. All of these benefits had substantial value to Teva, and are compensation that it could not have obtained even if it had litigated and won the patent case. These payments caused Teva to stay out of the market longer than it otherwise would have done. And Takeda made these payments to Mylan in exchange for its agreeing to delay entry with its generic ACTOS and ACTO*plus* met products. In short, Takeda made large, unjustified payments to Teva to delay entry into the markets.

VII. ANTICOMPETITIVE EFFECTS OF THE SCHEME AND AGREEMENTS

163. Defendants' conduct delayed and substantially diminished the sale of generic ACTOS and ACTO*plus* met in the United States. But for Defendants' illegal conduct, generic drug manufacturers would have entered the market unimpeded and competed on the merits against ACTOS and ACTO*plus* met. Generic drug manufacturers of ACTOS would have been able to compete as early as January 17, 2011. Generic drug manufacturers of ACTO*plus* met would have been able to compete as early as February 25, 2011. Defendants' conduct

unlawfully delayed and diminished the savings that purchasers of ACTOS and ACTO*plus* met and their generic equivalents would have garnered from unimpaired generic competition.

164. Defendants' conduct harmed Plaintiffs and the End-Payor Classes by depriving them of: (i) a marketplace in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (ii) the most cost efficient means of distribution. Contrary to the purpose of the Hatch-Waxman Act, Defendants' anticompetitive conduct enabled them to: (i) delay the entry of less expensive generic versions of ACTOS and ACTO*plus* met in the United States; (ii) fix, raise, maintain, or stabilize the price of ACTOS and ACTO*plus* met; and (iii) permit Takeda to maintain a monopoly in the United States market for ACTOS and its generic equivalents.

165. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the End-Payor Classes have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial.

VIII. CLASS ACTION ALLEGATIONS

166. Plaintiffs bring this action as two class actions, under FED. R. CIV. P. 23(a) and (b)(3), on behalf of themselves and the following similarly situated end-payors:

ACTOS Class:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for ACTOS and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "ACTOS Class"), from January 17, 2011 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "ACTOS Class Period").

ACTO*plus* met Class:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for ACTO*plus* met and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "ACTO*plus* met Class"), from February 25, 2011 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "ACTO*plus* met Class Period").

167. The following persons and entities are excluded from each of the above-described proposed Classes:

a. Defendants and their officers, directors, employees, parent corporations, subsidiaries, affiliates, representatives and/or agents;

b. All federal or state governmental entities, except cities, towns or municipalities with self-funded prescription drug plans;

c. All persons or entities that purchased ACTOS and/or ACTO*plus* met or the AB-rated generic equivalent for purposes of resale and/or directly from Defendants or their affiliates;

d. Fully insured health care plans (*i.e.*, health care plans that purchased insurance from a third-party payer covering 100% of a 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. Pharmacy Benefit Managers without capitation agreements; and

g. The Court, Court personnel and any members of their immediate families.

168. Members of each of the End-Payor Classes are so numerous that joinder is impracticable. On information and belief, each Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

169. As to each of the Classes, Plaintiffs' claims are typical of those of each of the Class members. As to each Class, Plaintiffs and Class members were damaged by the same wrongful conduct of Defendants, *i.e.*, as a direct and proximate result of Defendants' wrongful conduct, they paid artificially inflated prices for ACTOS and/or ACTO*plus* met and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

170. As to each of the Classes, Plaintiffs will fairly and adequately protect and represent the interests of the Class. As to each of the Classes, Plaintiffs' interests are coincident with, and not antagonistic to, the interests of the Class members.

171. Plaintiffs are represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

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

173. As to the ACTOS Class, questions of law and fact common to the Class include, but are not limited to:

a. whether Defendants conspired to willfully maintain and/or enhance Takeda's monopoly power over ACTOS and its generic equivalents;

b. whether Takeda submitted improper patent information describing the '584 Patent and '404 Patent as purported drug product patents covering ACTOS;

c. whether Defendants conspired to suppress generic competition to ACTOS;

d. whether Takeda and Mylan, Teva, Ranbaxy and/or Actavis entered into unlawful agreements in restraint of trade;

e. whether, pursuant to such agreements in restraint of trade, Mylan, Teva, Ranbaxy, and/or Actavis agreed to delay their entry into the market with generic ACTOS;

f. whether, pursuant to such agreements in restraint of trade, Takeda paid Mylan, Teva, Ranbaxy, and/or Actavis;

g. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were for a purpose other than delayed entry of generic ACTOS;

h. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

i. whether the Exclusionary Payment Agreements are unlawful under the rule of reason by reason because of large and unjustified payments from Takeda to generic Defendants ;

j. whether the Exclusionary Payment Agreements are per se unlawful because they restrict competition outside the exclusionary scope of Takeda's patents;

k. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride;

l. whether the law requires definition of a relevant market when direct proof of market power or monopoly power is available and, if so, the definition of the relevant market;

m. whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

n. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and Class members; and

o. the quantum of aggregate overcharge damages to Plaintiffs and Class members.

174. As to the ACTO*plus* met Class, questions of law and fact common to the Class include, but are not limited to:

a. whether Takeda, Mylan, and/or Teva conspired to suppress generic competition to ACTO*plus* met;

b. whether Takeda, Mylan, and/or Teva entered into unlawful agreements in restraint of trade;

c. whether, pursuant to such agreements in restraint of trade, Mylan and/or Teva agreed to delay their entry into the market with generic ACTO*plus* met;

d. whether, pursuant to such agreements in restraint of trade, Takeda paid Mylan and/or Teva;

e. whether Takeda's payments to Mylan and/or Teva were for a purpose other than delayed entry of generic ACTO*plus* met;

f. whether Takeda's payments to Mylan and/or Teva were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

g. whether the Exclusionary Payment Agreements are unlawful under the rule of reason by reason because of large and unjustified payments from Takeda to generic Defendants ;

h. whether the Exclusionary Payment Agreements are per se unlawful because they restrict competition outside the exclusionary scope of Takeda's patents;

i. whether Takeda possessed market power in the relevant market;

j. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

k. whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

l. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and Class members; and

m. the quantum of aggregate overcharge damages to Plaintiffs and Class members.

175. As to each Class, class action treatment is the 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 as a class action, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in the management of this action as a class action.

176. As to each Class, Plaintiffs know of no special difficulty that would be encountered in this action that would preclude its maintenance as a class action.

177. As to each Class, certification of the Class is appropriate under FED. R. CIV. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual Class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

178. As to each Class, Defendants' wrongful actions are generally applicable to the Class members as a whole, for which Plaintiffs seek, *inter alia*, damages and equitable remedies.

179. As to each Class, absent a class action, Defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on Plaintiffs and Class members.

IX. INTERSTATE AND INTRASTATE COMMERCE

180. At all relevant times, Takeda manufactured, promoted, distributed, and sold substantial amounts of ACTOS and ACTO*plus* met in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

181. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted

flow of commerce across state and national lines in connection with the sale of ACTOS and ACTO*plus* met and their generic equivalents.

182. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

183. Defendants' anticompetitive conduct also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic ACTOS and ACTO*plus* met to end-payors inside each respective state. The complete foreclosure of generic ACTOS and ACTO*plus* met directly impacted and disrupted commerce for end-payors within each state (and will continue to do so).

184. During the relevant time period, ACTOS, ACTO*plus* met, and their generic equivalents were shipped into each state and were sold to or paid for by end-payors in each state. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in each state because ACTOS, ACTO*plus* met, and their generic equivalents were sold to end-payors in each state at supracompetitive prices and Defendants entered into unlawful anticompetitive agreements that affected commerce in each state.

X. MONOPOLY POWER AND MARKET DEFINITION REGARDING ACTOS

185. At all relevant times, Takeda had monopoly power and, at a minimum, market power, over ACTOS and its generic equivalents because it had the power to maintain the price of ACTOS at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

186. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for ACTOS by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

187. At all relevant times, at competitive price levels, ACTOS did not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTOS. Other oral Type 2 diabetes medicines are not AB-rated to ACTOS, cannot be automatically substituted for ACTOS by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTOS, and thus, are not economic substitutes for ACTOS.

188. ACTOS is part of the Type 2 diabetes drug class called thiazolidinediones. Thiazolidinediones, like a few other antidiabetic classes of drugs, are often referred to as "insulin sensitivity enhancers" due to their ability to decrease the body's resistance to insulin. Unique to thiazolidinediones, however, is that they increase certain levels of proteins—those that are more sensitive to insulin—and thus are the primary means by which a patient's blood sugar levels may be lowered. Due to their differing effect within the body, thiazolidinediones are significantly unique in their efficacy, safety, and side effect profile. These attributes play a critical role in doctors' selection of the most appropriate antidiabetic for a particular patient.

189. Due to, among other reasons, doctors' perception of ACTOS's lower association with heart failure, death, and liver toxicity, ACTOS is significantly differentiated from other drugs in the thiazolidinedione class. For these and other clinical reasons, substantial numbers of doctors prefer ACTOS to other thiazolidinedione drugs (*e.g.*, Avandia (rosiglitazone)). For example, patients aged 65 and older who take Avandia (rosiglitazone) have a higher rate of death and a greater risk of heart failure when compared with similar patients taking ACTOS.

190. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTOS. At all relevant times, Takeda's price for ACTOS was at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs. Takeda never lowered the price of ACTOS in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

191. Takeda needed to control only ACTOS and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTOS at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of ACTOS would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTOS.

192. Takeda knew that entry of a generic version of ACTOS would be a uniquely significant market event. Takeda predicted that, unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTOS would take substantial unit sales from Takeda. For example, ACTOS did not lose substantial sales when generic versions of other branded Type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTOS would immediately cause branded ACTOS to lose well more than half of its unit sales. Likewise, Mylan, Ranbaxy, Actavis, and Teva estimated that their generic versions of ACTOS would take essentially all of their sales away from branded ACTOS and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

193. Takeda, Mylan, Teva, Ranbaxy, and Actavis predicted that the competitive impact of generic ACTOS products would be substantial. Among other things, Defendants predicted

that the availability of generic ACTOS would deliver well more than a billion dollars of savings to consumers.

194. At all relevant times, Takeda sold ACTOS at prices well in excess of its marginal costs and the ACTOS competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of Plaintiffs and the ACTOS Class members.

195. Takeda had, and exercised, the power to exclude and restrict competition to ACTOS and its AB-rated bioequivalents.

196. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

197. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is oral pioglitazone hydrochloride for the treatment of adults with Type 2 diabetes (*i.e.*, ACTOS and its AB-rated generic equivalents). At all relevant times, Takeda profitably maintained the price of pioglitazone hydrochloride well above competitive levels.

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

199. At all relevant times, Takeda's market share in the relevant geographic market was 100%, confirming its monopoly power.

XI. MARKET POWER AND MARKET DEFINITION REGARDING ACTO*PLUS* MET

200. At all relevant times, Takeda had market power over ACTO*plus* met and its generic equivalents because it had the power to maintain the price of ACTO*plus* met at

supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

201. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for ACTO*plus* met by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

202. At all relevant times, at competitive price levels ACTO*plus* met did not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTO*plus* met. Other oral Type 2 diabetes medicines are not AB-rated to ACTO*plus* met, cannot be automatically substituted for ACTO*plus* met by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTO*plus* met, and thus, are not economic substitutes for ACTO*plus* met.

203. For clinical reasons, ACTO*plus* met is sufficiently unique from other Type 2 diabetes drugs as it is specifically targeted to, and taken by, patients who have not sufficiently improved their blood sugar levels by taking either metformin or pioglitazone alone.

204. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTO*plus* met. At all relevant times, Takeda's price for ACTO*plus* met was at least 60% above its marginal cost of production and at least 40% above its marginal cost, including marketing costs. Takeda never lowered the price of ACTO*plus* met in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

205. Takeda needed to control only ACTO*plus* met and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTO*plus* met at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of

ACTO*plus* met would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTO*plus* met.

206. Takeda knew that entry of a generic version of ACTO*plus* met would be a uniquely significant market event. Takeda predicted that unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTO*plus* met would take substantial unit sales from Takeda. For example, ACTO*plus* met did not lose substantial sales when generic versions of other branded type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTO*plus* met would immediately cause branded ACTO*plus* met to lose well more than half of its unit sales. Likewise, Mylan and Teva estimated that their generic versions of ACTO*plus* met would take essentially all of their sales away from branded ACTO*plus* met and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

207. Takeda, Mylan, and Teva predicted the competitive impact of generic ACTO*plus* met products would be substantial. Among other things, Defendants predicted that the availability of generic ACTO*plus* met would deliver hundreds of millions of dollars of savings to consumers.

208. At all relevant times, Takeda sold ACTO*plus* met at prices well in excess of its marginal costs and ACTO*plus* met's competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of Plaintiffs and the ACTO*plus* met Class members.

209. Takeda had, and exercised, the power to exclude and restrict competition to ACTO*plus* met and its AB-rated bioequivalents.

210. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

211. To the extent Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is a fixed unit dose of oral pioglitazone hydrochloride and biguanide for the treatment of adults with Type 2 diabetes (*i.e.*, ACTO*plus* met and its AB-rated generic equivalents). During all relevant times, Takeda profitably maintained the price of ACTO*plus* met well above competitive levels.

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

213. At all relevant times, Takeda's market share in the relevant geographic market was 100%, confirming its market power.

XII. MARKET EFFECTS AND DAMAGES TO THE CLASSES

214. But for the anticompetitive conduct alleged above, generic competition for ACTOS would have begun as early as January 17, 2011, and generic competition for ACTO*plus* met would have begun as early as February 25, 2011.

215. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting ACTOS and ACTO*plus* met from generic competition. Defendants' unlawful actions allowed Takeda to maintain a monopoly and exclude competition in the market for ACTOS and its generic equivalents, and maintain supracompetitive prices for ACTO*plus* met, to the detriment of Plaintiffs and the members of the Classes. Defendants' anticompetitive conduct delayed and impaired generic

competition and unlawfully enabled Takeda to sell ACTOS and ACTO*plus* met without timely generic competition.

216. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of a branded drug for some or all of their purchases. As more generic drug manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition between the generic drug manufacturers, and, correspondingly, the branded drug loses even more of its market share. This price competition enables purchasers to (i) purchase generic versions of a branded drug at substantially lower prices, and (ii) purchase the branded drug at a reduced price. Consequently, branded drug manufacturers have a keen financial interest in delaying and impairing generic drug competition, which, in turn causes purchasers to experience substantial increases in costs.

217. But for Defendants' anticompetitive conduct, end-payors, such as Plaintiffs and Class members, would have paid less by (i) substituting less-expensive AB-rated generic ACTOS and/or ACTO*plus* met for the more expensive branded ACTOS and/or ACTO*plus* met, (ii) paying reduced prices on their remaining branded ACTOS and/or ACTOplus met purchases, and/or (iii) purchasing generic ACTOS and/or ACTO*plus* met at lower prices sooner.

218. Moreover, due to Defendants' anticompetitive conduct, other generic drug manufacturers were discouraged from and/or delayed in (i) developing and marketing generic versions of ACTOS and/or ACTO*plus* met, and/or (ii) challenging the validity or infringement of Takeda's patents in court.

219. At all relevant times during the Class Period, Plaintiffs and the End-Payor Class members indirectly purchased substantial amounts of ACTOS and/or ACTO*plus* met. As a

direct and proximate result of Defendants' illegal conduct, Plaintiffs and the Class members were compelled to pay, and did pay, artificially inflated prices for ACTOS and/or ACTO*plus* met and their generic equivalents. Plaintiffs and the Class members paid prices substantially greater than the prices they otherwise would have paid absent Defendants' illegal conduct because Class members: (i) were deprived of the opportunity to purchase lower-priced generic ACTOS and/or ACTO*plus* met instead of expensive branded ACTOS and/or ACTO*plus* met, and (ii) paid artificially inflated prices for ACTOS and/or ACTO*plus* met and their generic equivalents.

220. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiffs and Class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and/or ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial.

221. Defendants' unlawful conduct deprived Plaintiffs and Class members of the benefits of competition that the antitrust laws were designed to ensure.

XIII. ANTITRUST IMPACT

222. Overcharges for pharmaceuticals at a higher level of distribution generally result in higher prices at every level below.

223. Wholesalers and retailers passed on the inflated prices of branded ACTOS and ACTO*plus* met and AB-rated generic ACTOS and ACTO*plus* met to Plaintiffs and Class members.

224. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

225. The inflated prices paid by Plaintiffs and Class members are traceable to, and the direct, proximate and foreseeable result of, Defendants' overcharges.

226. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for ACTOS and ACTO*plus* met results in higher prices at every level below. Herbert Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE* p. 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

227. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

228. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

229. The inflated prices the members of the Classes paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

XIV. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda)

230. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

231. At all relevant times, Takeda possessed substantial market power (*i.e.*, monopoly power) with respect to ACTOS and its generic equivalents. Takeda possessed the power to

control prices in, prevent prices from falling in, and exclude competitors from the sale of ACTOS and its generic equivalents.

232. Through the overarching anticompetitive scheme, as alleged extensively above, Takeda willfully maintained its monopoly power with respect to ACTOS and its generic equivalents, using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the ACTOS Class members thereby. Takeda's exclusionary conduct pursuant to this anticompetitive scheme included (i) submitting improper patent information describing the '584 Patent and '404 Patent as drug product patents for ACTOS, (ii) entering into the Exclusion Payment Agreements with Mylan, Ranbaxy, and Actavis, with respect to ACTOS, (iii) intentionally creating a "bottleneck" to prevent later-filing generic manufacturers from entering the market before August 17, 2011, (iv) including the acceleration clauses in the agreements with Mylan, Ranbaxy, and Actavis with the purpose and effect of deterring Teva from unraveling the anticompetitive agreements, and (v) paying off Teva with the same purpose and effect.

233. It was Takeda's conscious objective to further its dominance of the sale of ACTOS and its generic equivalents by and through the overarching anticompetitive scheme.

234. Takeda's scheme harmed competition as alleged in detail above.

235. As a direct and proximate result of Takeda's illegal and monopolistic conduct, as alleged herein, Plaintiffs and ACTOS Class members were injured.

236. By engaging in the foregoing wrongful conduct, Takeda intentionally and wrongfully maintained monopoly power over the sale of ACTOS and its generic equivalents, in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

g. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

h. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of ACTOS in Minnesota by members of the ACTOS Class.

i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

j. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

k. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

l. N.H. Rev. Stat. Ann. §§ 356.3, with respect to purchases of ACTOS in New Hampshire by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

p. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

q. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of ACTOS in Puerto Rico by members of the ACTOS Class.

r. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases in Rhode Island by members of the ACTOS Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

t. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by members of the ACTOS Class who reside in Utah.

u. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

v. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

237. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

238. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

SECOND CLAIM FOR RELIEF
Attempted Monopolization Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda)

239. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

240. Takeda, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Takeda's conscious objective to control prices and/or to exclude competition in the relevant market.

241. The natural, intended, and foreseeable consequence of Takeda's overarching anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

242. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Takeda would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

243. As a direct and proximate result of Takeda's illegal and monopolistic conduct, Plaintiffs and the ACTOS Class members were harmed as alleged in detail above.

244. By engaging in the foregoing conduct, Takeda intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

g. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

h. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of ACTOS in Minnesota by members of the ACTOS Class.

i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

j. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

k. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

l. N.H. Rev. Stat. Ann. §§ 356.3, et *seq.*, with respect to purchases of ACTOS in New Hampshire by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

p. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

q. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of ACTOS in Puerto Rico by members of the ACTOS Class.

r. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the ACTOS Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

t. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by members of the ACTOS Class who reside in Utah.

u. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

v. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

245. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

246. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

THIRD CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda and Mylan)

247. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

248. The Exclusion Payment Agreement between Takeda and Mylan regarding ACTOS involves (i) a large and unjustified payment from Takeda to Mylan, and (ii) an agreement by Mylan to delay marketing its generic ACTOS. The payment from Takeda to Mylan under the Agreement was the *quid pro quo* for Mylan's agreement to delay marketing its generic version of ACTOS. Absent the payment, Mylan would not have agreed to delay marketing its generic versions of ACTOS and would have entered the market sooner than it did. The acceleration clause in the agreement is in unreasonable restraint of trade.

249. The purpose and effect of the payment flowing from Takeda to Mylan under the agreement was to delay generic competition to ACTOS. There is and was no legitimate, non-

pretextual, procompetitive business justification for the payment or the restraint of trade that outweighs their harmful effect. Even if there were some such conceivable justification, the payment and restraint were not necessary to achieve such a purpose.

250. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Mylan was to allocate 100% of the market for ACTOS and its generic equivalents in the United States to Takeda, delay the sale of generic ACTOS products, and fix the price at which consumers and other end-payors would pay for ACTOS and its generic equivalents at the higher, branded price.

251. The Exclusion Payment Agreement harmed competition.

252. As a direct and proximate result of Takeda's and Mylan's unlawful restraint of trade, Plaintiffs and ACTOS Class members paid artificially inflated prices for ACTOS and its generic equivalents as described herein, and were harmed as a result.

253. By engaging in the foregoing conduct, Takeda and Mylan intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-102, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code § 553.4, *et seq.*, with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTOS in Kansas by members of the ACTOS Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTOS Minnesota by members of the ACTOS Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

l. Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTOS in New York by members of the ACTOS Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTOS in the Commonwealth of Puerto Rico by members of the ACTOS Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of ACTOS in Rhode Island by members of the ACTOS Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTOS in Tennessee by members of the ACTOS Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by members of the ACTOS Class who reside in Utah.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTOS in Vermont by members of the ACTOS Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

254. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Mylan's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

255. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

FOURTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda and Ranbaxy)

256. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

257. The Exclusion Payment Agreement between Takeda and Ranbaxy regarding ACTOS involves (i) a large and unjustified payment from Takeda to Ranbaxy, and (ii) an agreement by Ranbaxy to delay marketing its generic versions of ACTOS. The payment from Takeda to Ranbaxy under the Agreement was the *quid pro quo* for Ranbaxy's agreement to delay

marketing its generic versions of ACTOS. Absent the payment, Ranbaxy would not have agreed to delay marketing its generic versions of ACTOS, and would have entered the market sooner than it did. The acceleration clause in the agreement is in unreasonable restraint of trade.

258. The purpose and effect of the payment flowing from Takeda to Ranbaxy under the Exclusion Payment Agreement was to delay generic competition to ACTOS. There is and was no legitimate, non-pretextual, procompetitive business justification for the payment or the restraint that outweighs their harmful effect. Even if there were some such conceivable justification, the payment and restraint were not necessary to achieve such a purpose.

259. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Ranbaxy was to allocate 100% of the market for ACTOS and its generic equivalents in the United States to Takeda, delay the sales of generic ACTOS products, and fix the price at which consumers and other end-payors pay for ACTOS and its generic equivalents at the higher, branded price.

260. The Exclusion Payment Agreement harmed competition.

261. As a direct and proximate result of Takeda's and Ranbaxy's unlawful restraint of trade, Plaintiffs and ACTOS Class members paid artificially inflated prices for ACTOS and its generic equivalents as described herein, and were harmed as a result.

262. By engaging in the foregoing conduct, Takeda and Ranbaxy intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code § 553.4, *et seq.*, with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTOS in Kansas by members of the ACTOS Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

h. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

i. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of ACTOS Minnesota by members of the ACTOS Class.

j. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTOS in New York by members of the ACTOS Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTOS in the Commonwealth of Puerto Rico by members of the ACTOS Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.* with respect to purchases of ACTOS in Rhode Island by members of the ACTOS Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTOS in Tennessee by members of the ACTOS Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by residents of Utah who are members of the ACTOS Class.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTOS in Vermont by members of the ACTOS Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

263. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Ranbaxy's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

264. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

FIFTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda and Actavis)

265. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

266. The Exclusion Payment Agreement between Takeda and Actavis regarding ACTOS involves (i) a large and unjustified payment from Takeda to Actavis, and (ii) an agreement by Actavis to delay marketing its generic versions ACTOS. The payment from Takeda to Actavis under the Agreement was the *quid pro quo* for Actavis's agreement to delay marketing its generic versions of ACTOS. Absent the payment, Actavis would not have agreed to delay marketing its generic versions of ACTOS, and would have entered the market sooner than it did. The acceleration clause in the agreement is in unreasonable restraint of trade.

267. The purpose and effect of the payment flowing from Takeda to Actavis under the Exclusion Payment Agreement was to delay generic competition to ACTOS. There is and was no legitimate, non-pretextual, procompetitive business justification for the payment or the restraint that outweighs their harmful effect. Even if there were some such conceivable justification, the payment and restraint were not necessary to achieve such a purpose.

268. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Actavis was to allocate 100% of the market for ACTOS and its generic equivalents in the United States to Takeda, delay the sales of generic ACTOS products, and fix the price at which consumers and other end-payors pay for ACTOS and its generic equivalents at the higher, branded price.

269. The Exclusion Payment Agreement harmed competition.

270. As a direct and proximate result of Takeda's and Actavis's unlawful restraint of trade, Plaintiffs and ACTOS Class members paid artificially inflated prices for ACTOS and its generic equivalents as described herein, and were harmed as a result.

271. By engaging in the foregoing conduct, Takeda and Actavis intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code § 553.4, *et seq.*, with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTOS in Kansas by members of the ACTOS Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTOS Minnesota by members of the ACTOS Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTOS in New York by members of the ACTOS Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTOS in the Commonwealth of Puerto Rico by members of the ACTOS Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.* with respect to purchases of ACTOS in Rhode Island by members of the ACTOS Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTOS in Tennessee by members of the ACTOS Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by residents of Utah who are members of the ACTOS Class.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTOS in Vermont by members of the ACTOS Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

272. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Actavis's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States,

the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

273. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

SIXTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against Takeda and Teva)

274. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

275. The Exclusion Payment Agreement between Takeda and Teva involves (i) large and unjustified payments from Takeda to Teva, and (ii) an agreement by Teva to delay marketing its generic versions of ACTOS. The payments from Takeda to Teva under the Agreement were the *quid pro quo* for Teva's agreement to delay marketing its generic versions of ACTOS. Absent the payments, Teva would not have agreed to delay marketing its generic versions of ACTOS, and would have entered the market sooner than it did.

276. The purpose and effect of the payments flowing from Takeda to Teva under the Exclusion Payment Agreement was to delay generic competition to ACTOS. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

277. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Teva was to allocate 100% of the market for ACTOS and its generic equivalents in the United States to Takeda, delay the sales of generic ACTOS products, and fix the price at

which consumers and other end-payors pay for ACTOS and its generic equivalents at the higher, branded price.

278. The Exclusion Payment Agreement harmed competition.

279. As a direct and proximate result of Takeda's and Teva's unlawful restraint of trade, Plaintiffs and ACTOS Class members paid artificially inflated prices for ACTOS and its generic equivalents as described herein, and were harmed as a result.

280. By engaging in the foregoing conduct, Takeda and Teva intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code § 553.4, et seq., with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTOS in Kansas by members of the ACTOS Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTOS Minnesota by members of the ACTOS Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTOS in New York by members of the ACTOS Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTOS in the Commonwealth of Puerto Rico by members of the ACTOS Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of ACTOS in Rhode Island by members of the ACTOS Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTOS in Tennessee by members of the ACTOS Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by residents of Utah who are members of the ACTOS Class.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTOS in Vermont by members of the ACTOS Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

281. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Teva's antitrust violations, in that Plaintiffs and ACTOS Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

282. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

SEVENTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTOS Class Against All Defendants)

283. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

284. Through an overarching anticompetitive scheme, including the Exclusion Payment Agreements between Takeda and each of Mylan, Ranbaxy, Actavis, and Teva, all Defendants conspired to block and delay the entry into the market of generic ACTOS. The purpose and effect of the conspiracy was to allocate 100% of the market for ACTOS and its generic equivalents in the United States to Takeda, delay the sale of generic ACTOS products, and fix the price at which consumers and other end-payors would pay for ACTOS and its generic equivalents at the higher, branded price. Absent the conspiracy, generic versions of ACTOS would have entered the market sooner than they did.

285. There is and was no legitimate, non-pretextual, procompetitive business justification for the conspiracy that outweighs its harmful effect. Even if there were some such

conceivable justification, the unlawful Exclusion Payment Agreements between and among the Defendants were not necessary to achieve such a purpose.

286. Each Defendant committed at least one overt act in furtherance of the conspiracy. Among other things, (i) each Defendant agreed to the same entry date, (ii) each Defendant agreed to pay or accept an exclusion payment and to unreasonably restrain trade in order to agree to the same entry date, (iii) Mylan, Ranbaxy, and Actavis agreed that Takeda could advise the other Defendants of the market entry date to which Defendants had agreed, (iv) Mylan, Ranbaxy, and Actavis agreed with Takeda to include an acceleration clause in their respective Exclusion Payment Agreements, (v) Mylan, Ranbaxy, and Actavis agreed with Takeda that it could advise the other Defendants of the existence of the acceleration clauses, and (vi) Mylan and Takeda agreed to permit Takeda to grant a license to Teva to market ACTO*plus* met beginning on the date Mylan began selling ACTO*plus* met, with the purpose and effect of enticing Teva to drop its challenge to the ACTOS patents and to Takeda's unlawful listing of the '584 Patent and '404 Patent as drug product claims covering ACTOS.

287. The unlawful conspiracy harmed competition.

288. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and ACTOS Class members paid artificially inflated prices for ACTOS and its generic equivalents as described herein, and were harmed as a result.

289. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the ACTOS Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTOS in California by members of the ACTOS Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the ACTOS Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTOS in Illinois by members of the ACTOS Class.

e. Iowa Code § 553.4, et seq., with respect to purchases of ACTOS in Iowa by members of the ACTOS Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTOS in Kansas by members of the ACTOS Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTOS in Maine by members of the ACTOS Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the ACTOS Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTOS Minnesota by members of the ACTOS Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the ACTOS Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the ACTOS Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the ACTOS Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the ACTOS Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTOS in New York by members of the ACTOS Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the ACTOS Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the ACTOS Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the ACTOS Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTOS in the Commonwealth of Puerto Rico by members of the ACTOS Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of ACTOS in Rhode Island by members of the ACTOS Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the ACTOS Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTOS in Tennessee by members of the ACTOS Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by residents of Utah who are members of the ACTOS Class.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTOS in Vermont by members of the ACTOS Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the ACTOS Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the ACTOS Class.

290. Plaintiffs and ACTOS Class members have been (and will continue to be) injured in their business or property by reason of Defendants' antitrust violations, in that Plaintiffs and the ACTOS Class (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

291. Plaintiffs and ACTOS Class members seek damages and multiple damages as permitted by law for their injuries.

EIGHTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTO*plus* met Class Against Takeda and Mylan)

292. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

293. The Exclusion Payment Agreement between Takeda and Mylan regarding ACTO*plus* met involves (i) large and unjustified payments from Takeda to Mylan, and (ii) an agreement by Mylan to delay marketing its generic versions of ACTO*plus* met. The payments from Takeda to Mylan under the Exclusion Payment Agreement were the *quid pro quo* for Mylan's agreement to delay marketing its generic versions of ACTO*plus* met. Absent the payments, Mylan would not have agreed to delay marketing its generic versions of ACTO*plus* met and would have entered the market sooner than it did. The acceleration clauses in the agreements between Takeda and Mylan are in unreasonable restraint of trade.

294. The purpose and effect of the payments flowing from Takeda to Mylan under the Exclusion Payment Agreement was to delay generic competition to ACTO*plus* met. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments and restraints that outweighs their harmful effect. Even if there were some such conceivable justification, the payments and restraints were not necessary to achieve such a purpose.

295. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Mylan was to allocate 100% of the market for ACTO*plus* met and its generic equivalents in the United States to Takeda, delay the sale of generic ACTO*plus* met products, and fix the price at which consumers and other end-payors pay for ACTO*plus* met and its generic equivalents at the higher, branded price.

296. The Exclusion Payment Agreement harmed competition.

297. As a direct and proximate result of Takeda's and Mylan's unlawful restraint of trade, Plaintiffs and ACTO*plus* met Class members paid artificially inflated prices for ACTO*plus* met and its generic equivalents as described herein, and were harmed as a result.

298. By engaging in the foregoing conduct, Takeda and Mylan intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTO*plus* met in Arizona by members of the ACTO*plus* met Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTO*plus* met in California by members of the ACTO*plus* met Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTO*plus* met in the District of Columbia by members of the ACTO*plus* met Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTO*plus* met in Illinois by members of the ACTO*plus* met Class.

e. Iowa Code § 553.4, et seq., with respect to purchases of ACTO*plus* met in Iowa by members of the ACTO*plus* met Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTO*plus* met in Kansas by members of the ACTO*plus* met Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTO*plus* met in Maine by members of the ACTO*plus* met Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTO*plus* met in Michigan by members of the ACTO*plus* met Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTO*plus* met Minnesota by members of the ACTO*plus* met Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTO*plus* met in Mississippi by members of the ACTO*plus* met Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTO*plus* met in Nebraska by members of the ACTO*plus* met Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTO*plus* met in Nevada by members of the ACTO*plus* met Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTO*plus* met in New Mexico by members of the ACTO*plus* met Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTO*plus* met in New York by members of the ACTO*plus* met Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTO*plus* met in North Carolina by members of the ACTO*plus* met Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTO*plus* met in North Dakota by members of the ACTO*plus* met Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTO*plus* met in Oregon by members of the ACTO*plus* met Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTO*plus* met in the Commonwealth of Puerto Rico by members of the ACTO*plus* met Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of ACTO*plus* met in Rhode Island by members of the ACTO*plus* met Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTO*plus* met in South Dakota by members of the ACTO*plus* met Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTO*plus* met in Tennessee by members of the ACTO*plus* met Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTO*plus* met in Utah by residents of Utah who are members of the ACTO*plus* met Class.

w. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of ACTO*plus* met in Vermont by members of the ACTO*plus* met Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTO*plus* met in West Virginia by members of the ACTO*plus* met Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTO*plus* met in Wisconsin by members of the ACTO*plus* met Class.

299. Plaintiffs and ACTO*plus* met Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Mylan's antitrust violations, in that Plaintiffs and ACTO*plus* met Class members (i) were denied the opportunity to purchase lower-priced generic ACTO*plus* met, and (ii) paid higher prices for branded ACTO*plus* met than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

300. Plaintiffs and ACTO*plus* met Class members seek damages and multiple damages as permitted by law for their injuries.

NINTH CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted by Plaintiffs and the ACTO*plus* met Class Against Takeda and Teva)

301. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

302. The Exclusion Payment Agreement between Takeda and Teva regarding ACTO*plus* met involves (i) large and unjustified payments from Takeda to Teva, and (ii) an agreement by Teva to delay marketing its generic versions of ACTO*plus* met. The payments from Takeda to Teva under the Exclusion Payment Agreement were the *quid pro quo* for Teva's agreement to delay marketing its generic versions of ACTO*plus* met. Absent the payments, Teva

would not have agreed to delay marketing its generic versions of ACTO*plus* met, and would have entered the market sooner than it did.

303. The purpose and effect of the payments flowing from Takeda to Teva under the Exclusion Payment Agreement was to delay generic competition to ACTO*plus* met. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

304. The purpose and effect of the unlawful Exclusion Payment Agreement between Takeda and Teva was to allocate 100% of the market for ACTO*plus* met and its generic equivalents in the United States to Takeda, delay the sale of generic ACTO*plus* met products, and fix the price at which consumers and other end-payors pay for ACTO*plus* met and its generic equivalents at the higher, branded price.

305. The Exclusion Payment Agreement harmed competition.

306. As a direct and proximate result of Takeda's and Teva's unlawful restraint of trade, Plaintiffs and ACTO*plus* met Class members paid artificially inflated prices for ACTO*plus* met and its generic equivalents as described herein, and were harmed as a result.

307. By engaging in the foregoing conduct, Takeda and Teva intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of ACTO*plus* met in Arizona by members of the ACTO*plus* met Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of ACTO*plus* met in California by members of the ACTO*plus* met Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of ACTO*plus* met in the District of Columbia by members of the ACTO*plus* met Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of ACTO*plus* met in Illinois by members of the ACTO*plus* met Class.

e. Iowa Code § 553.4, et seq., with respect to purchases of ACTO*plus* met in Iowa by members of the ACTO*plus* met Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of ACTO*plus* met in Kansas by members of the ACTO*plus* met Class.

g. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of ACTO*plus* met in Maine by members of the ACTO*plus* met Class.

h. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of ACTO*plus* met in Michigan by members of the ACTO*plus* met Class.

i. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of ACTO*plus* met Minnesota by members of the ACTO*plus* met Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTO*plus* met in Mississippi by members of the ACTO*plus* met Class.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of ACTO*plus* met in Nebraska by members of the ACTO*plus* met Class.

l. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of ACTO*plus* met in Nevada by members of the ACTO*plus* met Class.

m. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of ACTO*plus* met in New Mexico by members of the ACTO*plus* met Class.

n. New York General Business Law § 340, *et seq.*, with respect to purchases of ACTO*plus* met in New York by members of the ACTO*plus* met Class.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of ACTO*plus* met in North Carolina by members of the ACTO*plus* met Class.

p. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases of ACTO*plus* met in North Dakota by members of the ACTO*plus* met Class.

q. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of ACTO*plus* met in Oregon by members of the ACTO*plus* met Class.

r. 10 L.P.R.A. § 258 with respect to purchases of ACTO*plus* met in the Commonwealth of Puerto Rico by members of the ACTO*plus* met Class.

s. R.I. Gen. Laws §§ 6-36-4, *et seq.* with respect to purchases of ACTO*plus* met in Rhode Island by members of the ACTO*plus* met Class.

t. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases of ACTO*plus* met in South Dakota by members of the ACTO*plus* met Class.

u. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of ACTO*plus* met in Tennessee by members of the ACTO*plus* met Class.

v. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTO*plus* met in Utah by residents of Utah who are members of the ACTO*plus* met Class.

w. Vt. Stat. Ann. tit. 9 § 2453, *et seq.*, with respect to purchases of ACTO*plus* met in Vermont by members of the ACTO*plus* met Class.

x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of ACTO*plus* met in West Virginia by members of the ACTO*plus* met Class.

y. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of ACTO*plus* met in Wisconsin by members of the ACTO*plus* met Class.

308. Plaintiffs and ACTO*plus* met Class members have been (and will continue to be) injured in their business or property by reason of Takeda's and Teva's antitrust violations, in that Plaintiffs and ACTO*plus* met Class members (i) were denied the opportunity to purchase lower-priced generic ACTO*plus* met, and (ii) paid higher prices for branded ACTO*plus* met than they

would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

309. Plaintiffs and ACTO*plus* met Class members seek damages and multiple damages as permitted by law for their injuries.

TENTH CLAIM FOR RELIEF
State Consumer Protection Violations
(Asserted by Plaintiffs and the ACTOS Class Against All Defendants)

310. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

311. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and ACTOS Class members were deprived of the opportunity to purchase a generic equivalent of ACTOS and forced to pay higher prices for their ACTOS requirements.

312. For years, there was a gross disparity between the price that Plaintiffs and the Class members paid for the brand product when compared to the less expensive generic products, which should have been available.

313. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

a. Defendants have engaged in unfair or unconscionable acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, *et seq.*

b. Defendants have engaged in unfair or unconscionable acts or

practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

c. Defendants have engaged in unfair or unconscionable acts or practices or made false representations in violation of D.C. Code §§ 28-3904, *et seq.*

d. Defendants have engaged in unfair or unconscionable acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/2, *et seq.*

e. Defendants have engaged in unfair or unconscionable acts or practices in violation of Kan. Stat. Ann, §§ 50-627, *et seq.*

f. Defendants have engaged in unfair or unconscionable acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207; *et seq.*

g. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mass. Gen. Laws Ch. 93A, *et seq.*

h. Defendants have engaged in deceptive or fraudulent acts or practices in violation of Minn. Stat. §§ 831, 325D.44 and 325F.69.

i. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mo. Ann. Stat. §§ 407.020, *et seq.*

j. Defendants have engaged in unfair or unconscionable acts or practices in violation of Neb. Rev. Stat. §§ 59.1602, *et seq.*

k. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:2, *et seq.*

l. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.M. Stat. Ann. §§ 57-12-3, *et seq.*

m. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.* Plaintiffs seek single damages under this statute.

n. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq.*

o. Defendants have engaged in deceptive or fraudulent acts or practices in violation of N.D. Cent. Code §§ 51-15-03, *et seq.*

p. Defendants have engaged in unfair or unconscionable acts or practices in violation of 73 Pa. State. Ann. §§ 201-3, *et seq.*

q. Defendants have engaged in unfair or unconscionable acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-2, *et seq.*

r. Defendants have engaged in deceptive or fraudulent acts or practices in violation of S.D, Codified Laws §§ 37-24-6, *et seq.*

s. Defendants have engaged in unfair or unconscionable acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2453, *et seq.*

t. Defendants have engaged in unfair or unconscionable acts or practices in violation of W. Va. Code §§ 46A-6-104 *et seq.*

314. Plaintiffs and the ACTOS Class have been injured in their business and property by reason of Defendants' unfair or unconscionable acts or practices alleged herein. Their injury consists of paying higher prices for ACTOS than they would have paid in the absence of such violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

ELEVENTH CLAIM FOR RELIEF
State Consumer Protection Violations
(Asserted by Plaintiffs and the ACTO*plus* met Class Against Defendants Takeda, Mylan, and Teva)

315. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

316. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and ACTO*plus* met Class members were deprived of the opportunity to purchase a generic equivalent of ACTO*plus* met and forced to pay higher prices for their ACTO*plus* met requirements.

317. For years, there was a gross disparity between the price that Plaintiffs and the Class members paid for the brand product when compared to the less expensive generic products, which should have been available.

318. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer fraud laws:

a. Defendants have engaged in unfair or unconscionable acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

b. Defendants have engaged in unfair or unconscionable acts or practices or made false representations in violation of D.C. Code §§ 28-3901, *et seq.*

c. Defendants have engaged in unfair or unconscionable acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*

d. Defendants have engaged in unfair or unconscionable acts or practices in violation of Kan. Stat. Ann, §§ 50-623, *et seq.*

e. Defendants have engaged in unfair or unconscionable acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207; *et seq.*

f. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mass. Gen. Laws Ch. 93A, *et seq.*

g. Defendants have engaged in deceptive or fraudulent acts or practices in violation of Minn. Stat. §§ 831, 325D.44 and 325F.69.

h. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mo. Ann. Stat. §§ 407.020, *et seq.*

i. Defendants have engaged in unfair or unconscionable acts or practices in violation of Neb. Rev. Stat. §§ 59.1602, *et seq.*

j. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:2, *et seq.*

k. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.M. Stat. Ann. §§ 57-12-3, *et seq.*

l. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.*

m. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq.*

n. Defendants have engaged in deceptive or fraudulent acts or practices in violation of N.D. Cent. Code §§ 51-15-03, *et seq.*

o. Defendants have engaged in unfair or unconscionable acts or practices in violation of 73 Pa. State. Ann. §§ 201-3, *et seq.*

p. Defendants have engaged in unfair or unconscionable acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-2, *et seq.*

q. Defendants have engaged in deceptive or fraudulent acts or practices in violation of S.D, Codified Laws §§ 37-24-6, *et seq.*

r. Defendants have engaged in unfair or unconscionable acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2453, *et seq.*

s. Defendants have engaged in unfair or unconscionable acts or practices in violation of W. Va. Code §§ 46A-6-101 *et seq.*

319. Plaintiffs and the ACTO*plus* met Class have been injured in their business and property by reason of Defendants' unfair or unconscionable acts or practices alleged herein. Their injury consists of paying higher prices for ACTO*plus* met than they would have paid in the absence of such violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

TWELFTH CLAIM FOR RELIEF
Unjust Enrichment Regarding ACTOS
(Asserted by Plaintiffs and the ACTOS Class Against All Defendants)

320. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

321. Defendants have benefited from splitting the supracompetitive profits on Takeda's ACTOS sales resulting from the unlawful and inequitable acts alleged herein.

322. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for ACTOS by Plaintiffs and ACTOS Class members.

323. Plaintiffs and ACTOS Class members have conferred upon Defendants an economic benefit in the nature of profits resulting from unlawful overcharges and supracompetitive profits—to the economic detriment of Plaintiffs and ACTOS Class members.

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

325. It also would be futile for Plaintiffs and ACTOS Class members to exhaust any remedy they might have against any immediate intermediary in the chain of distribution from which they indirectly purchased ACTOS. Any such intermediaries are not liable and would not compensate Plaintiffs and ACTOS Class members for harm caused by Defendants.

326. The economic benefit in the form of overcharges and unlawful profits derived by Defendants through charging supracompetitive and artificially inflated prices for ACTOS is a direct and proximate result of Defendants' unlawful practices.

327. The financial benefits derived by Defendants rightfully belong to Plaintiffs and ACTOS Class members because they paid anticompetitive and supracompetitive prices during the ACTOS Class Period that wrongfully inured to the benefit of Defendants.

328. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendants to retain any of the overcharges for ACTOS derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged herein.

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

330. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and ACTOS Class members.

331. Plaintiffs and ACTOS Class members have no adequate remedy at law.

THIRTEENTH CLAIM FOR RELIEF
Unjust Enrichment Regarding ACTO*plus* met
(Asserted by Plaintiffs and the ACTO*plus* met Class Against Takeda, Mylan, and Teva)

332. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

333. Takeda, Mylan, and Teva benefited from splitting the supracompetitive profits on Takeda's ACTO*plus* met sales resulting from the unlawful and inequitable acts alleged herein.

334. Takeda's, Mylan's, and Teva's financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for ACTO*plus* met by Plaintiffs and ACTOS Class members.

335. Plaintiffs and ACTO*plus* met Class members have conferred upon Takeda, Mylan, and Teva an economic benefit in the nature of profits resulting from unlawful overcharges and supracompetitive profits—to the economic detriment of Plaintiffs and ACTO*plus* met Class members.

336. It would be futile for Plaintiffs and ACTO*plus* met Class members to seek a remedy from any party with whom they had privity of contract. Takeda, Mylan, and Teva have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and ACTO*plus* met Class members.

337. It also would be futile for Plaintiffs and ACTO*plus* met Class members to exhaust any remedy against any immediate intermediary in the chain of distribution from which they

indirectly purchased ACTO*plus* met. Any such intermediaries are not liable and would not compensate Plaintiffs and ACTO*plus* met Class members for harm caused by Takeda, Mylan, and Teva.

338. The economic benefit of in the form of overcharges and unlawful profits derived by Takeda, Mylan, and Teva through charging supracompetitive and artificially inflated prices for ACTO*plus* met is a direct and proximate result of Takeda's, Mylan's, and Teva's unlawful practices.

339. The financial benefits derived by Takeda, Mylan, and Teva rightfully belong to Plaintiffs and ACTO*plus* met Class members because Plaintiffs and ACTO*plus* met Class members paid anticompetitive and supracompetitive prices during the ACTO*plus* met Class Period that wrongfully inured to the benefit of Takeda, Mylan, and Teva.

340. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for the Takeda, Mylan, and Teva to retain any of the overcharges for ACTO*plus* met derived from Takeda, Mylan, and Teva's unfair and unconscionable methods, acts, and trade practices alleged herein.

341. Takeda, Mylan, and Teva should be compelled to disgorge in a common fund for the benefit of Plaintiffs and ACTO*plus* met Class members all unlawful or inequitable proceeds received by them.

342. A constructive trust should be imposed upon all unlawful or inequitable sums received by Takeda, Mylan, and Teva traceable to Plaintiffs and ACTO*plus* met Class members.

343. Plaintiffs and the ACTO*plus* met Class have no adequate remedy at law.

XV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, individually and on behalf of both Classes, respectfully demand judgment for the following relief:

A. Certification of this action as a class action, pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), direction of reasonable Class notice, pursuant to by Fed. R. Civ. P. 23(c)(2), appointment of Plaintiffs as representatives of the Classes, and appointment of Plaintiffs' counsel as Class Counsel;

B. A finding that Defendants' wrongful conduct alleged herein violated the statutes set forth above, and constitutes unjust enrichment under the common law of all states and jurisdictions within the United States, except Indiana and Ohio;

C. Joint and several judgments against Defendants in favor of Plaintiffs and the Classes;

D. Equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

E. Plaintiffs' and Class members' damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

F. Attorneys' fees, litigation expenses, and costs of suit; and

G. Such other and further relief as necessary to correct the anticompetitive market effects caused by Defendants' unlawful conduct, and as the Court deems just.

XVI. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs, individually and on behalf of the proposed Classes, respectfully demand a trial by jury on all issues so triable.

Dated: August 22, 2014

Respectfully Submitted,

s/ Karen M. Leser-Grenon

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CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2014, a copy of the foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

Dated: October 6, 2014

s/ Karen M. Leser-Grenon
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EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION

ORDER
13-CV-09244 (RA) (RLE)

RONALD L. ELLIS, United States Magistrate Judge:

Plaintiffs filed a Consolidated Amended Class Action Complaint ("CAC") on May 20, 2014. (Doc. 50) Since the filing of this CAC, the Parties have, at times, corresponded with the Court via email, at times, corresponded with the Court via postal mail and, at other times, corresponded with the Court via the Electronic Case Files ("ECF") system.

On July 8, Defendants informed the Court that they intended to file a Motion to Dismiss. Defendants requested two things: (1) that the Court, when deciding the Motion to Dismiss, consider patent litigation settlement agreements upon which some of Plaintiffs' allegations were founded, and (2) that the Court allow Defendants to file said settlement agreements under seal. Defendants argued that these agreements should not be publicly available because of the confidential business information they contained.

Defendants filed their Motion to Dismiss on July 11. (Doc. 94) On July 25, Plaintiffs asked permission to file an amended CAC in order to respond to issues raised in Defendants' Motion to Dismiss and that request was granted by District Judge Abrams on July 30. (Doc. 112) Plaintiffs filed an amended CAC on August 22. (Doc. 113) That same day, in response to the concerns about confidentiality that Defendants had voiced on July 8, Plaintiffs asked permission to file a redacted version of the CAC which would replace the August 22 filing. This amendment was requested more than 21 days after service of the July 25 CAC. Rule 15(a)(2) of

the Federal Rules of Civil Procedure states that a party may amend its pleading more than 21 days after service only with the opposing party's written consent or the Court's leave. Plaintiffs sent a physical copy of the redacted CAC to the Court on September 10 without leave of the Court. This redacted CAC was not filed. Plaintiffs thereupon provided the Court with Defendants' written consent to file the redacted CAC on September 18, 2014, thus meeting the requirements of Rule 15(a)(2).

IT IS HEREBY ORDERED that the Plaintiffs refile their redacted CAC with the Court.

IT IS HEREBY ORDERED that all parties correspond with the Court through the ECF system.

SO ORDERED this 3rd day of October 2014.
New York, New York

The Honorable Ronald L. Ellis
United States Magistrate Judge