Anthony J. Viola
Andre K. Cizmarik
EDWARDS ANGELL PALMER & DODGE LLP
Attorneys for Plaintiffs
Takeda Pharmaceutical Company Limited,
Takeda Pharmaceuticals North America, Inc.
and Takeda Global Research and Development Center, Inc.
750 Lexington Ave.
New York, NY 10022
(212) 308-4411

'09 CIV 4665

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc., Plaintiffs, v. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA., Inc. Defendants.	Civil Action No. COMPLAINT

Plaintiffs, Takeda Pharmaceutical Company Limited (formerly known as Takeda Chemical Industries, Ltd.) ("TPC"), Takeda Pharmaceuticals North America, Inc. ("TPNA"), and Takeda Global Research & Development Center, Inc. ("Takeda Global") (collectively, "Takeda") by their undersigned counsel, for their Complaint against defendants Teva Pharmaceutical Industries, Ltd. ("Teva Pharms."), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Teva"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over the defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because defendants are doing business in this jurisdiction.

Parties

2. TPC is a Japanese corporation having its corporate headquarters in Osaka, Japan and principal place of business in Osaka, Japan. TPNA is a wholly owned U.S. subsidiary of Takeda American Holdings, Inc., which is a wholly owned U.S. subsidiary of TPC. TPNA has its corporate headquarters and principal place of business in Deerfield, Illinois and is organized under the laws of Delaware. Takeda Global is a wholly owned subsidiary of TPNA. Takeda Global has its corporate headquarters and principal place of business in Lake Forest, Illinois, and is organized under the laws of Delaware.

3. TPC is engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including ACTOS® which is comprised of the active ingredient pioglitazone hydrochloride, and ACTOPLUS MET®, which comprises a combination of the active ingredients pioglitazone hydrochloride and metformin hydrochloride.

4. Upon information and belief, Teva USA is incorporated in the state of Delaware and has a place of business in North Wales, Pennsylvania. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 91-155 was filed under the name of Teva

USA. Teva USA supplies, markets, sells and distributes pharmaceuticals to all fifty states, including at least New York. Upon information and belief, Teva USA has a facility in Pomona, New York at which it carries out pharmaceutical manufacturing, laboratory and warehousing activities.

5. Upon information and belief, defendant Teva Pharms. is a corporation incorporated under the laws of Israel, and has its corporate headquarters in Israel. Upon information and belief, Teva Pharms. has actual control over the activities of Teva USA which is a wholly owned subsidiary of Teva Pharms. Upon information and belief, ANDA No. 77-210 was filed under the name of Teva.

6. Upon information and belief, Teva is currently transacting business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Teva derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and the Southern District of New York. Upon information and belief, Teva USA is registered with the N.Y. State Department of State, Division of Corporations, to do business as a foreign corporation in New York. By filing its ANDA, Teva has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, that Teva expects or should reasonably expect to have consequences in the State of New York.

The New Drug Applications

7. TPNA sells pioglitazone-containing drug products under the trade name ACTOS® in the United States pursuant to the United States Food and Drug Administration's approval of an NDA held by TPNA (NDA No. 21-073).

8. ACTOS® is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes (non-insulin-dependent diabetes mellitus). ACTOS® is indicated for monotherapy. ACTOS® is also indicated for use in combination with a sulfonylurea, metformin, or insulin when diet and exercise plus the single agent does not result in adequate glycemic control.

9. The approval letter for ACTOS®, with approved labeling, was issued by the FDA on July 15, 1999. The approval was for both monotherapy and combination therapy, based upon the FDA's consideration of clinical studies, presented in a single NDA, for both types of therapies.

10. TPNA sells drug products containing a combination of pioglitazone hydrochloride and metformin hydrochloride under the trade name ACTOPLUS MET® in the United States pursuant to the United States Food and Drug Administration's ("FDA") approval of a New Drug Application ("NDA") held by Takeda Global (NDA No. 21-842).

11. ACTOPLUS MET® is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes (non-insulin-dependent diabetes mellitus).

12. The approval letter for ACTOPLUS MET®, with approved labeling, was issued by the FDA on August 29, 2005.

The Patents in Suit

13. United States Patent No. 5,965,584 ("the '584 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 12, 1999 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka and assigned to plaintiff TPC. The '584 patent claims, inter alia, 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, such as metformin. The '584 patent covers the drug approved in NDA No. 21-842.

14. Plaintiff TPC has been and still is the owner through assignment of the '584 patent, which expires on June 19, 2016.

15. United States Patent No. 6,329,404 ("the '404 patent"), entitled "Pharmaceutical composition," a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on December 11, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '404 patent claims, *inter alia*, a pharmaceutical composition comprising pioglitazone or salts thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea, such as repaglinide or 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.

16. Plaintiff TPC has been and still is the owner through assignment of the '404 patent, which expires on June 19, 2016.

17. United States Patent No. 6,166,043 ("the '043 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit C**, was duly issued on December 26, 2000 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '043 patent claims, inter alia, methods for reducing the amount of active components administered to a diabetic patient, which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin.

18. Plaintiff TPC has been and still is the owner through assignment of the '043 patent, which expires on June 19, 2016.

19. United States Patent No. 6,172,090 ("the '090 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit D**, was duly issued on January 9, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '090 patent claims, inter alia, methods for reducing the side effects of active components administered to a diabetic patient, which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin, as the active components.

20. Plaintiff TPC has been and still is the owner through assignment of the '090 patent, which expires on June 19, 2016.

21. United States Patent No. 6,211,205 ("the '205 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit E**, was duly issued on April 3, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '205 patent claims, *inter alia*, methods for reducing the amount of active components administered to a diabetic patient, which comprises administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea).

22. Plaintiff TPC has been and still is the owner through assignment of the '205 patent, which expires on June 19, 2016.

23. United States Patent No. 6,271,243 ("the '243 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit F**, was duly issued on August 7, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned

to plaintiff TPC. The '243 patent claims, *inter alia,* methods for reducing the side effects of active components administered to a diabetic patient, which comprises administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin preparation.

24. Plaintiff TPC has been and still is the owner through assignment of the '243 patent, which expires on June 19, 2016.

25. United States Patent No. 6,303,640 ("the '640 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit G**, was duly issued on October 16, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '640 patent claims, *inter alia,* methods for reducing the side effects of active components administered to a diabetic patient, which comprises administering a therapeutically effective amount of a pioglitazone or salt thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea).

26. Plaintiff TPC has been and still is the owner through assignment of the '640 patent, which expires on August 9, 2016.

27. Plaintiff TPC has granted an exclusive license to plaintiff TPNA under the '584 patent, the '404 patent, the '043 patent, the '090 patent, the '205 patent, the '243 patent, and the '640 patent (collectively, "Takeda Patents").

28. In accordance with its exclusive license, plaintiff TPNA sells pioglitazone-containing drug products under the trade name ACTOS®, among others, in the United States. Sales of TPNA's pioglitazone-containing drug products are made pursuant to approval by the FDA of, among others, NDA No. 21-073.

29. Plaintiff TPC manufactures the ACTOS® drug products sold by TPNA.

30. In accordance with its exclusive license, plaintiff TPNA sells drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS MET® in the United States. Sales of TPNA's drug products containing a combination of pioglitazone and metformin are made pursuant to approval by the FDA of NDA No. 21-842.

31. Plaintiff Takeda Global is the holder of NDA No. 21-842, under which TPNA sells ACTOPLUS MET®.

32. Plaintiff TPC manufactures the drug products containing a combination of pioglitazone and metformin, that are sold by TPNA.

33. Plaintiffs TPC, TPNA and Takeda Global will be both substantially and irreparably harmed by infringement of any of the Takeda Patents. There is no adequate remedy at law.

I. TEVA's ANDA No. 91-155

COUNT I

(DIRECT INFRINGEMENT OF THE '584 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

34. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

35. Upon information and belief, defendant Teva USA, under the control of defendant Teva Pharms., filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 91-155) seeking approval to market (i) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/500 mg, and (ii) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/850 mg.

36. By this ANDA filing, Teva has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Teva has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

37. By its ANDA filing, Teva seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '584 patent.

38. By a letter (the "Notice Letter") dated April 14, 2009, Teva USA informed plaintiffs that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about April 15, 2009, NDA holder, Takeda Global, received the Notice Letter. On or about April 17, 2009, patent owner, TPC, received a duplicate original of the Notice Letter.

39. The Notice Letter, purporting to be Teva USA's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Teva's opinion, the '584 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product."

40. Teva's filing of ANDA No. 91-155 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '584 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

41. Teva's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '584 patent.

42. Unless Teva is enjoined from infringing, contributing to and/or inducing the infringement of the '584 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II

(INDUCEMENT OF INFRINGEMENT OF METHOD CLAIMS OF THE '584 PATENT UNDER 35 U.S.C. § 271(b))

43. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

44. On information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '584 patent, immediately or imminently upon approval of the ANDA.

45. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of Type 2 Diabetes.

46. Additionally, upon information and belief, Teva's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Teva and to customers of Teva. Teva will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the

desire, to actively induce, aid and abet infringement of the '584 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement of the '584 patent.

47. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Teva intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Teva's generic combination pioglitazone and metformin drug products.

48. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

49. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '584 patent. Plaintiffs have no adequate remedy at law.

COUNT III

(CONTRIBUTORY INFRINGEMENT OF THE '584 PATENT UNDER 35 U.S.C. § 271(c))

50. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

51. On information and belief, Teva seeks FDA approval of ANDA 91-155 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

52. Upon information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '584 patent, immediately or imminently upon approval of the ANDA.

53. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

54. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '584 patent. Plaintiffs have no adequate remedy at law.

COUNT IV

(DIRECT INFRINGEMENT OF THE '043 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

55. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

56. Upon information and belief, defendant Teva USA, under the control of defendant Teva Pharms, filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 91-155) seeking approval to market (i) tablets comprising a combination of 15 mg/500 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) tablets comprising a combination of 15 mg/850 mg of pioglitazone hydrochloride/metformin hydrochloride.

57. By this ANDA filing, Teva has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Teva has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

58. By its ANDA filing, Teva seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '043 patent.

59. By a Notice Letter dated April 14, 2009, Teva USA informed plaintiffs that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about April 15, 2009, NDA holder, Takeda Global, received the Notice Letter. On or about April 17, 2008, patent owner, TPC, received a duplicate original of the Notice Letter.

60. The Notice Letter, purporting to be Teva USA's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Teva's opinion, the '043 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Teva USA's product."

61. Teva's filing of ANDA No. 91-155 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '043 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

62. Teva's manufacture, use, offer for sale, and/or sale (or the inducement thereof, or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '043 patent.

63. Unless Teva is enjoined from infringing, contributing to and/or inducing the infringement of the '043 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V

(INDUCEMENT OF INFRINGEMENT OF THE METHOD CLAIMS OF THE '043 PATENT UNDER 35 U.S.C. § 271(b))

64. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

65. On information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '043 patent, immediately or imminently upon approval of the ANDA.

66. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly to reduce the amount of active componenets administered to the diabetic patient.

67. Additionally, upon information and belief, Teva's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Teva and to customers of Teva. Teva will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the

desire, to actively induce, aid and abet infringement of the '043 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement of the '043 patent.

68. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Teva intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Teva's generic combination pioglitazone and metformin drug products.

69. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

70. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '043 patent. Plaintiffs have no adequate remedy at law.

COUNT VI

(CONTRIBUTORY INFRINGEMENT OF THE '043 PATENT UNDER 35 U.S.C. § 271(c))

71. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

72. On information and belief, Teva seeks FDA approval of ANDA 91-155 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

73. On information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '043 patent, immediately or imminently upon approval of the ANDA.

74. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

75. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '043 patent. Plaintiffs have no adequate remedy at law.

COUNT VII

(DIRECT INFRINGEMENT OF THE '090 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

76. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

77. Upon information and belief, defendant Teva USA, under the control of defendant Teva Pharms., filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 91-155) seeking approval to market (i) tablets comprising a combination of 15 mg/500 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) tablets comprising a combination of 15 mg/850 mg of pioglitazone hydrochloride/metformin hydrochloride.

78. By this ANDA filing, Teva has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Teva has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

79. By its ANDA filing, Teva seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '090 patent.

80. By a Notice Letter dated April 14, 2009, Teva USA informed plaintiffs that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about April 15, 2009, NDA holder, Takeda Global, received the Notice Letter. On or about April 17, 2009, patent owner, TPC, received a duplicate original of the Notice Letter.

81. The Notice Letter, purporting to be Teva USA's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Teva's opinion, the '090 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Teva USA's product."

82. Teva's filing of ANDA No. 91-155 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '090 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

83. Teva's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '090 patent.

84. Unless Teva is enjoined from infringing, contributing to and/or inducing the infringement of the '090 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII

(INDUCEMENT OF INFRINGEMENT OF THE METHOD CLAIMS OF THE '090 PATENT UNDER 35 U.S.C. § 271(b))

85. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

86. On information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '090 patent, immediately or imminently upon approval of the ANDA.

87. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly for reducing the side effects of active components administered to a diabetic patient.

88. Additionally, upon information and belief, Teva's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Teva and to customers of Teva. Teva will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the

desire, to actively induce, aid and abet infringement of the '090 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement of the '090 patent.

89. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Teva intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Teva's generic combination pioglitazone and metformin drug products.

90. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

91. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '090 patent. Plaintiffs have no adequate remedy at law.

COUNT IX

(CONTRIBUTORY INFRINGEMENT OF THE '090 PATENT UNDER 35 U.S.C. § 271(c))

92. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

93. On information and belief, Teva seeks FDA approval of ANDA 91-155 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

94. On information and belief, approval of ANDA 91-155 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '090 patent, immediately or imminently upon approval of the ANDA.

95. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

96. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '090 patent. Plaintiffs have no adequate remedy at law.

II. TEVA's ANDA No. 77-210

COUNT X

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '584 PATENT UNDER 35 U.S.C. § 271(b))

97. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

98. On information and belief, defendant Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 77-210) seeking approval to market (i) tablets comprising 15 mg of pioglitazone hydrochloride, (ii) tablets comprising 30 mg of pioglitazone hydrochloride, and (iii) tablets comprising 45 mg of pioglitazone hydrochloride.

99. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '584 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '584 patent.

100. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '584 patent and that use in such methods does not require a physician to co-prescribe pioglitazone with a biguanide, e.g., metformin. Further, patients routinely take pioglitazone in combination with additional active components, such as biguanides for use in methods covered by the '584 patent. The intended use of pioglitazone in combination therapy to treat diabetes would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy

benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

101. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '584 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

102. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and biguanides, and such information will promote the use of pioglitazone in combination with biguanides, e.g., metformin. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '584 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

103. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone,

namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and a biguanide, e.g., metformin, also applies to Teva's generic pioglitazone-containing drug product.

104. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

105. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '584 patent. Plaintiffs have no adequate remedy at law.

COUNT XI

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '404 PATENT UNDER 35 U.S.C. § 271(b))

106. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

107. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in the '404 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '404 patent.

108. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '404 patent and that use in such method does not require a physician to co-prescribe pioglitazone with an insulin secretion enhancer (e.g., a sulfonylurea). Further, patients routinely take pioglitazone in combination with additional active components, such as insulin secretion enhancers for use in

methods covered by the '404 patent. The intended use of pioglitazone in combination therapy to treat diabetes would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

109. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '404 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

110. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and insulin secretion enhancers such as a sulfonylurea and such information will promote the use of pioglitazone in combination with an insulin secretion enhancer, such as a sulfonylurea. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '404 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

111. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone, namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and an insulin secretion enhancer (e.g., a sulfonylurea), also applies to Teva's generic pioglitazone-containing drug product.

112. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

113. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '404 patent. Plaintiffs have no adequate remedy at law.

COUNT XII

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '043 PATENT UNDER 35 U.S.C. § 271(b))

114. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

115. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '043 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '043 patent.

116. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '043 patent and that use in such methods does not require a physician to co-prescribe pioglitazone with a biguanide, e.g., metformin. Further, patients routinely take pioglitazone in combination with additional active components, such as biguanides for use in methods covered by the '043 patent. The intended use of pioglitazone in combination therapy to reduce the amount of active components used in such therapy would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

117. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '043 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

118. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and biguanides, e.g., metformin and such information will promote the use of pioglitazone in combination with biguanides, e.g.,

metformin. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '043 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

119. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone, namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and a biguanide, e.g., metformin, also applies to Teva's generic pioglitazone-containing drug product.

120. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

121. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '043 patent. Plaintiffs have no adequate remedy at law.

COUNT XIII

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '090 PATENT UNDER 35 U.S.C. § 271(b))

122. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

123. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale and/or sale of a drug

product which is marketed and sold for use in a method claimed in one or more claims of the '090 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '090 patent.

124. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '090 patent and that use in such methods does not require a physician to co-prescribe pioglitazone with a biguanide, e.g., metformin. Further, patients routinely take pioglitazone in combination with additional active components, such as biguanides for use in methods covered by the '090 patent. The intended use of pioglitazone in combination therapy to reduce side effects of such therapy would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

125. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '090 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

126. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and biguanides, e.g., metformin and such information will promote the use of pioglitazone in combination with biguanides, e.g., metformin. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '090 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

127. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a given generic product with a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone, namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and a biguanide, e.g., metformin, also applies to Teva's generic pioglitazone-containing drug product.

128. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

129. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '090 patent. Plaintiffs have no adequate remedy at law.

COUNT XIV

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '205 PATENT UNDER 35 U.S.C. § 271(b))

130. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

131. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '205 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '205 patent.

132. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '205 patent and that use in such methods does not require a physician to co-prescribe pioglitazone with an insulin secretion enhancer (e.g., a sulfonylurea). Further, patients routinely take pioglitazone in combination with additional active components, such as insulin secretion enhancers for use in methods covered by the '205 patent. The intended use of pioglitazone in combination therapy to reduce the amount of active components used in such therapy would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

133. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in

combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '205 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

134. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and insulin secretion enhancers such as a sulfonylurea and such information will promote the use of pioglitazone in combination with insulin secretion enhancers. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '205 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

135. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone, namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and an insulin secretion

enhancer (e.g., a sulfonylurea), also applies to Teva's generic pioglitazone-containing drug product.

136. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

137. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '205 patent. Plaintiffs have no adequate remedy at law.

COUNT XV

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '243 PATENT UNDER 35 U.S.C. § 271(b))

138. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

139. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a methods claimed in one or more claims of the '243 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '243 patent.

140. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '243 patents and that use in such methods does not require a physician to co-prescribe pioglitazone with an insulin preparation. Further, patients routinely take pioglitazone in combination with additional active components, such as insulin preparations for use in methods covered by the '243 patent. The intended use of pioglitazone in combination therapy to treat a diabetic patient to reduce side effects of active components used in such therapy would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits

management companies, health care providers who establish drug formularies for their insurers and/or patients).

141. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '243 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

142. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and insulin preparations, and such information will promote the use of pioglitazone in combination with insulin preparations. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '243 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

143. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone,

namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and an insulin preparation, also applies to Teva's generic pioglitazone-containing drug product.

144. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

145. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '243 patent. Plaintiffs have no adequate remedy at law.

COUNT XVI

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '640 PATENT UNDER 35 U.S.C. § 271(b))

146. Plaintiffs TPC and TPNA repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

147. Upon information and belief, approval of ANDA 77-210 is substantially likely to result in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a methods claimed in one or more claims of the '640 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '640 patent.

148. Upon information and belief, Teva is aware or reasonably should be aware, of the widespread use of pioglitazone in the methods of one or more claims of the '640 patents and that use in such methods does not require a physician to co-prescribe pioglitazone with an insulin secretion enhancer (e.g., a sulfonylurea). Further, patients routinely take pioglitazone in combination with additional active components, such as insulin secretion enhancers for use in

methods covered by the '640 patent. The intended use of pioglitazone in combination therapy to reduce side effects of active components used in such therapy would be readily apparent to a customer of Teva (e.g., including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients).

149. Upon information and belief, Teva's proposed label for its pioglitazone drug products does not restrict the use of those products to only monotherapy. As is well known to Teva and its customers, the majority of patients treated with pioglitazone take it in combination with another antidiabetic drug, namely, such patients obtain treatment with pioglitazone in combination with a biguanide such as metformin, in combination with an insulin secretion enhancer such as a sulfonylurea, and/or treatment in combination with an insulin preparation. The beneficial effects of such combination therapy are well known to Teva and customers of Teva. On information and belief, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively induce, aid and abet, infringement of the '640 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

150. Additionally, upon information and belief, Teva's proposed label also provides, or will be required by the FDA to provide, information for patients regarding the co-administration of, and/or drug interactions between, pioglitazone and insulin secretion enhancers such as a sulfonylurea and that such information will promote the use of pioglitazone in combination with an insulin secretion enhancer. The beneficial effects of such co-administration and/or interactions are well known to customers of Teva. By including this information in its label, Teva will be marketing pioglitazone with specific intent, and/or with the desire to actively

induce, aid and abet, infringement of the '640 patent. Teva knows or reasonably should know that its proposed conduct will induce infringement.

151. Upon information and belief, Teva's generic marketing practices include listing generic products on its website and referring consumers to compare a given generic product with a corresponding brand name product. Upon information and belief, Teva intends to do the same for any approved generic pioglitazone, namely, Teva intends to list its generic product and refer consumers to Takeda's product, ACTOS®. Upon information and belief, such marketing practices are substantially likely to lead a consumer of generic pioglitazone to infer that prescribing information for ACTOS®, which includes directions relating to the use of combinations of ACTOS® and an insulin secretion enhancer (e.g., a sulfonylurea), also applies to Teva's generic pioglitazone-containing drug product.

152. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

153. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from infringing the '640 patent. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a.) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Teva's drug products for which it seeks FDA approval under either ANDA No. 91-155 or No. 77-210 or which contain the active ingredient pioglitazone, and/or inducing or contributing to the same, will infringe at least one claim of one or more of the Takeda Patents;

(b.) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that inducing the making, using, offering for sale, selling and/or importing of Teva's drug products under either ANDA No. 91-155 or No. 77-210 or which contain the active

ingredient pioglitazone, will infringe at least one claim of one or more of the Takeda Patents;

(c.) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that contributing to the making, using, offering for sale, selling and/or importing of Teva's drug products under either ANDA No. 91-155 or No. 77-210 or which contain the active ingredient pioglitazone will infringe at least one claim of one or more of the Takeda Patents;

(d.) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Teva to commercially make, use, sell, offer to sell or import any drug product containing pioglitazone be no earlier than the date following the expiration date of the last to expire of the Takeda Patents;

(e.) A permanent injunction restraining and enjoining against any infringement by defendants, their officers, agents, attorneys, or employees, or those acting in privity or concert with them, of one or more of the Takeda Patents through the commercial manufacture, use, sale, offer for sale or importation into the United States of any drug product containing pioglitazone, and/or any inducement of and/or any contribution to the same;

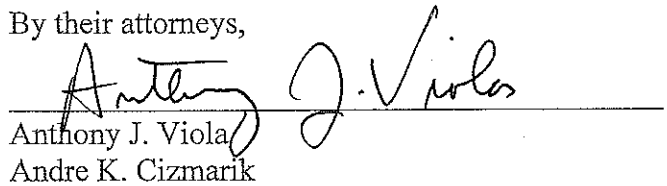
(f.) Attorneys' fees in this action under 35 U.S.C. § 285;

(g.) Such further and other relief as this Court may deem just and proper.

Dated: New York, New York
May 18, 2009

Takeda Pharmaceutical Company, Limited,
Takeda Pharmaceuticals, North America, Inc. and
Takeda Global Research & Development Center,
Inc.

By their attorneys,



Anthony J. Viola
Andre K. Cizmarik
EDWARDS ANGELL PALMER & DODGE LLP
750 Lexington Avenue
New York, NY 10022
(212) 308-4411

David G. Conlin (to be admitted *pro hac vice*)
Barbara L. Moore (to be admitted *pro hac vice*)
Kathleen B. Carr (to be admitted *pro hac vice*)
Adam P. Samansky (to be admitted *pro hac vice*)
EDWARDS ANGELL PALMER & DODGE LLP
111 Huntington Avenue
Boston, MA 02199-7613
(617) 439-4444

BOS 656607.9