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

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. Aurobindo Pharma Limited and Aurobindo Pharma USA Inc., Defendant.	Civil Action No. 10 CIV 1339 COMPLAINT

Plaintiffs, Takeda Pharmaceutical Company Limited (formerly known as Takeda Chemical Industries, Ltd.) ("TPC"), Takeda Pharmaceuticals North America, Inc. ("TPNA") (collectively, "Takeda") and Takeda Global Research & Development ("Takeda Global") by their undersigned counsel, for their Complaint against defendants Aurobindo Pharma Limited ("Aurobindo Ltd.") and Aurobindo Pharma USA Inc., ("Aurobindo Inc.") (collectively, "Aurobindo"), 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), and 281-83. 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 ACTOPLUS MET®, which comprises a combination of the active ingredients pioglitazone hydrochloride and metformin hydrochloride.

4. On information and belief, Aurobindo Ltd. is a company organized and existing under the laws of India, having its principal place of business in Hyderabad, Pradesh, India. Upon information and belief, ANDA No. 20-0823 was filed under the name of Aurobindo Ltd.

5. On information and belief, Aurobindo Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business in New Jersey. Upon information and belief, Aurobindo Inc. acts as the U.S. agent and distributor for Aurobindo Ltd.

6. On information and belief, Aurobindo Inc. sells generic drugs, manufactured and supplied by Aurobindo Ltd., throughout the United States, including New York. Further, Aurobindo Inc. has registered to do business with the New York Department of State.

7. On information and belief, Aurobindo Inc. is a wholly-owned subsidiary of Aurobindo Ltd. On information and belief, Aurobindo Ltd., directly or through its wholly-owned subsidiary, Aurobindo Inc., sells and markets pharmaceutical products throughout the United States, including in this Judicial District.

8. Upon information and belief, Aurobindo 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. Upon information and belief, Aurobindo 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 this Judicial District. By filing its ANDA, Aurobindo has committed, and unless enjoined, will continue to commit a tortious act without the State of New York, which Aurobindo expects or should reasonably expect to have consequences in the State of New York.

The New Drug Application

9. 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).

10. 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).

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

The Patents in Suit

12. 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. Claim 13 recites that pioglitazone and biguanide are administered as an admixture. The '584 patent covers the drug approved in NDA No. 21-842.

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

14. 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 B**, 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.

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

16. 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 C**, 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.

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

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

19. 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.

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

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

22. 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.

COUNT I

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

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

24. Upon information and belief, defendant Aurobindo, filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-0823) 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.

25. By this ANDA filing, Aurobindo 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, Aurobindo has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

26. By its ANDA filing, Aurobindo 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.

27. By a letter (the "Notice Letter") dated January 15, 2010, Aurobindo informed plaintiffs that Aurobindo had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about January 18, 2010, NDA holder, Takeda Global received the Notice Letter. On or about January 18, 2010, patent owner, TPC received a duplicate original of the Notice Letter.

28. The Notice Letter, purporting to be Aurobindo's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Aurobindo's opinion, "none of the claims of the listed patents," including the '584 patent, "will be infringed by Aurobindo's commercial manufacture, use or sale of its pioglitazone hydrochloride tablets . . . and/or that those claims are invalid or unenforceable."

29. Aurobindo's filing of ANDA No. 20-0823 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).

30. Aurobindo'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.

31. Unless Aurobindo 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))

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

33. On information and belief, approval of ANDA No. 20-0823 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.

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

35. Additionally, upon information and belief, Aurobindo'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 Aurobindo and to customers of Aurobindo. Aurobindo 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. Aurobindo knows or reasonably should know that its proposed conduct will induce infringement of the '584 patent.

36. Upon information and belief, Aurobindo intends to refer customers toTakeda'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 Aurobindo's generic combination pioglitazone and metformin drug products.

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

38. 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))

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

40. On information and belief, Aurobindo seeks FDA approval of ANDA 20-0823 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

41. Upon information and belief, approval of ANDA 20-0823 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.

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

43. 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))

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

45. Upon information and belief, Aurobindo filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-0823) 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.

46. By this ANDA filing, Aurobindo 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, Aurobindo has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

47. By its ANDA filing, Aurobindo 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.

48. By a Notice Letter dated January 15, 2010, Aurobindo informed plaintiffs that Aurobindo had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about January 18, 2010, NDA holder, Takeda Global received the Notice Letter. On or about January 18, 2010, patent owner, TPC received a duplicate original of the Notice Letter.

49. The Notice Letter, purporting to be Aurobindo's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Aurobindo's opinion, "none of the claims of the listed patents," including the '043 patent, "will be infringed by Aurobindo's commercial manufacture, use or sale of its pioglitazone hydrochloride tablets . . . and/or that those claims are invalid or unenforceable."

50. Aurobindo's filing of ANDA No. 20-0823 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).

51. Aurobindo'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.

52. Unless Aurobindo 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 '043 PATENT UNDER 35 U.S.C. § 271(b))

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

54. On information and belief, approval of ANDA 20-0823 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.

55. Upon information and belief, Aurobindo 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 components administered to the diabetic patient.

56. Additionally, upon information and belief, Aurobindo'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 Aurobindo and to customers of Aurobindo. Aurobindo 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. Aurobindo knows or reasonably should know that its proposed conduct will induce infringement of the '043 patent.

57. Upon information and belief, Aurobindo intends to 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 Aurobindo's generic combination pioglitazone and metformin drug products.

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

59. 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))

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

61. On information and belief, Aurobindo seeks FDA approval of ANDA 20-0823 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

62. On information and belief, approval of ANDA 20-0823 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.

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

64. 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))

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

66. Upon information and belief, Aurobindo filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-0823) 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.

67. By this ANDA filing, Aurobindo 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, Aurobindo has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

68. By its ANDA filing, Aurobindo 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.

69. By a Notice Letter dated January 15, 2010, Aurobindo informed plaintiffs that Auobindo had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about January 18, 2010, NDA holder, Takeda Global received the Notice Letter. On or about January 18, 2010, patent owner, TPC, received a duplicate original of the Notice Letter.

70. The Notice Letter, purporting to be Aurobindo's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Aurobindo's opinion, "none of the claims of the listed patents," including the '090 patent, "will be infringed by Aurobindo's commercial manufacture, use or sale of its pioglitazone hydrochloride tablets . . . and/or that those claims are invalid or unenforceable."

71. Aurobindo's filing of ANDA No. 20-0823 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).

72. Aurobindo'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.

73. Unless Aurobindo 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 '090 PATENT UNDER 35 U.S.C. § 271(b))

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

75. On information and belief, approval of ANDA 20-0823 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.

76. Upon information and belief, Aurobindo 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.

77. Additionally, upon information and belief, Aurobindo'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 Aurobindo and to customers of Aurobindo. Aurobindo 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. Aurobindo knows or reasonably should know that its proposed conduct will induce infringement of the '090 patent.

78. Upon information and belief, Aurobindo intends to 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 Aurobindo's generic combination pioglitazone and metformin drug products.

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

80. 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))

81. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 80 above.

82. On information and belief, Aurobindo seeks FDA approval of ANDA 20-0823 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

83. On information and belief, approval of ANDA 20-0823 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.

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

85. 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.

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 Aurobindo's drug products for which it seeks FDA approval or the active ingredients pioglitazone and metformin in combination, and/or inducing or contributing to the same, will infringe at least one claim 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 Aurobindo's drug products or the active ingredients pioglitazone and metformin in combination, 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 Aurobindo's drug products or the active ingredients pioglitazone and metformin in combination, 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 Aurobindo to commercially to make, use, sell, offer to sell or import pioglitazone in combination with metformin or any drug product containing pioglitazone in combination with metformin be no earlier than the date following the expiration date of the last to expire of the '584 patent, the '043 patent, or the '090 patent;

(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 the '584 patent, the '043 patent or the '090 patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of pioglitazone or any drug product containing pioglitazone in combination with metformin, 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
February 18, 2010

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
Joseph E. Czerniawski
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) 239-0100