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

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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. Sandoz, Inc. Defendant.	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 defendant Sandoz, Inc. ("Sandoz"), 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 DUETACT®, which comprises a combination of the active ingredients pioglitazone hydrochloride and glimepiride.

4. Upon information and belief, Sandoz is a corporation existing under the laws of the State of Colorado with its principal place of business in Princeton, New Jersey. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 20-1049 was filed under the name of Sandoz.

5. Upon information and belief, Sandoz sells, manufactures and/or distributes generic drugs, and considers itself to be one of the largest generic drug makers in the United States.

6. Upon information and belief, Sandoz 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, Sandoz 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, Sandoz has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, which Sandoz expects or should reasonably expect to have consequences in the State of New York. In addition, Sandoz is registered with the New York Department of State, Division of Corporations, to do business as a foreign corporation in New York.

The New Drug Application

7. TPNA sells drug products containing a combination of pioglitazone hydrochloride and glimepiride under the trade name DUETACT® 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. 21-925).

8. DUETACT® 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).

9. The approval letter for DUETACT®, with approved labeling, was issued by the FDA on July 28, 2006.

The Patents in Suit

10. 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 A**, 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 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.

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

12. 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 B**, 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 comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea).

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

14. 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 C**, 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 comprise administering a therapeutically effective amount of pioglitazone or salt thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea).

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

16. United States Patent No. 7,538,125 ("the '125 Patent") entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit D**, was duly issued on May 26, 2009 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka and assigned to TPC. The '125 Patent claims, inter alia, a pharmaceutical composition comprising pioglitazone or salts thereof, glimepiride and a physiologically acceptable carrier.

17. Plaintiff TPC has been and is still the owner through assignment of the '125 Patent, which expires on June 19, 2016.

18. Plaintiff TPC has granted an exclusive license to plaintiff TPNA under the '404 Patent, the '640 patent, the '205 patent, and the '125 patent (collectively, the "Takeda Patents").

19. In accordance with its exclusive license, plaintiff TPNA sells drug products containing a combination of pioglitazone and glimepiride under the trade name DUETACT® in the United States. Sales of TPNA's drug products containing a combination of pioglitazone and glimepiride are made pursuant to approval by the FDA of NDA No. 21-925.

20. Plaintiff Takeda Global is the holder of NDA No. 21-925, under which TPNA sells DUETACT.®

21. Plaintiff TPC manufactures the drug products containing a combination of pioglitazone and glimepiride 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 '404 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 Sandoz, filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-1049) seeking approval to market (i) tablets comprising a combination of 30 mg/2 mg of pioglitazone hydrochloride/glimepiride, and (ii) tablets comprising a combination of 30 mg/4 mg of pioglitazone hydrochloride/glimepiride.

25. By this ANDA filing, Sandoz 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/glimepiride drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Sandoz has indicated that its combination pioglitazone and glimepiride drug products are bioequivalent to Takeda's combination pioglitazone and glimepiride drug products.

26. By its ANDA filing, Sandoz seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' DUETACT® pioglitazone and glimepiride combination drug products prior to the expiration date of the '404 patent.

27. By a letter (the "Notice Letter") dated March 18, 2010, Sandoz informed plaintiffs that Sandoz had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about March 19, 2010, NDA holder, Takeda Global, received the Notice Letter. On or about March 23, 2010, patent owner, TPC, received a duplicate original of the Notice Letter.

28. The Notice Letter, purporting to be Sandoz's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Sandoz's opinion, the '404 patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz's Pioglitazone HCL/Glimepiride Tablets . . . ."

29. Sandoz's filing of ANDA No. 20-1049 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 or salts thereof and glimepiride before the expiration of the '404 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

30. Sandoz's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and glimepiride drug products will directly infringe at least one of the claims of the '404 patent.

31. Unless Sandoz is enjoined from infringing, contributing to and/or inducing the infringement of the '404 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 '404 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 20-1049 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 '404 patent, immediately or imminently upon approval of the ANDA.

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

35. Additionally, upon information and belief, Sandoz's proposed label for its combination pioglitazone and glimepiride products will instruct patients to take pioglitazone in combination with glimepiride for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Sandoz and to customers of Sandoz. Sandoz will be marketing its pioglitazone and glimepiride combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '404 patent. Sandoz knows or reasonably should know that its proposed conduct will induce infringement of the '404 patent.

36. Upon information and belief, Sandoz's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Sandoz intends to do the same for any approved generic pioglitazone and glimepiride combination drug product, namely Sandoz intends to list its generic product and refer customers to Takeda's product, DUETACT®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and glimepiride drug product to infer that prescribing information for DUETACT®, which includes directions relating to the use of a combination of pioglitazone and glimepiride, also applies to Sandoz's generic combination pioglitazone and glimepiride 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 '404 patent. Plaintiffs have no adequate remedy at law.

COUNT III

(CONTRIBUTORY INFRINGEMENT OF THE '404 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, Sandoz seeks FDA approval of ANDA 20-1049 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and glimepiride combination drug products.

41. Upon information and belief, approval of ANDA 20-1049 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 '404 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 '404 patent. Plaintiffs have no adequate remedy at law.

COUNT IV

(DIRECT INFRINGEMENT OF THE '205 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, defendant filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-1049) seeking approval to market (i) tablets comprising a combination of 30 mg/2 mg of pioglitazone hydrochloride/glimepiride, and (ii) tablets comprising a combination of 30 mg/4 mg of pioglitazone hydrochloride/glimepiride.

46. By this ANDA filing, Sandoz 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/glimepiride drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Sandoz has indicated that its combination pioglitazone and glimepiride drug products are bioequivalent to Takeda's combination pioglitazone and glimepiride drug products.

47. By its ANDA filing, Sandoz seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' DUETACT® pioglitazone and glimepiride combination drug products prior to the expiration date of the '205 patent.

48. By a Notice Letter dated March 18, 2010, Sandoz informed plaintiffs that Sandoz had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about March 19, 2010, NDA holder, Takeda Global, received the Notice Letter. On or about March 23, 2010, patent owner, TPC, received a duplicate original of the Notice Letter.

49. The Notice Letter, purporting to be Sandoz's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Sandoz's opinion, the '205 patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz's Pioglitazone HCL/Glimepiride Tablets . . . ."

50. Sandoz's filing of ANDA No. 20-1049 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 or salts thereof and glimepiride before the expiration of the '205 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

51. Sandoz's manufacture, use, offer for sale, and/or sale (or the inducement thereof, or contribution thereto) of its proposed combination pioglitazone and glimepiride drug products will directly infringe at least one of the claims of the '205 patent.

52. Unless Sandoz is enjoined from infringing, contributing to and/or inducing the infringement of the '205 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V

(INDUCEMENT OF INFRINGEMENT OF THE '205 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 20-1049 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 '205 patent, immediately or imminently upon approval of the ANDA.

55. Upon information and belief, Sandoz is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with glimepiride, 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, Sandoz's proposed label for its combination pioglitazone and glimepiride products will instruct patients to take pioglitazone in combination with glimepiride for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Sandoz and to customers of Sandoz. Sandoz will be marketing its pioglitazone and glimepiride combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '205 patent. Sandoz knows or reasonably should know that its proposed conduct will induce infringement of the '205 patent.

57. Upon information and belief, Sandoz's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Sandoz intends to do the same for any approved generic pioglitazone and glimepiride combination drug product, namely Sandoz intends to list its generic product and refer customers to Takeda's product, DUETACT®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and glimepiride drug product to infer that prescribing information for DUETACT®, which includes directions relating to the use of a combination of pioglitazone and glimepiride, also applies to Sandoz's generic combination pioglitazone and glimepiride 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 '205 patent. Plaintiffs have no adequate remedy at law.

COUNT VI

(CONTRIBUTORY INFRINGEMENT OF THE '205 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, Sandoz seeks FDA approval of ANDA 20-1049 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and glimepiride combination drug products.

62. On information and belief, approval of ANDA 20-1049 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 '205 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 '205 patent. Plaintiffs have no adequate remedy at law.

COUNT VII

(DIRECT INFRINGEMENT OF THE '640 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, defendant filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-1049) seeking approval to market (i) tablets comprising a combination of 30 mg/2 mg of pioglitazone hydrochloride/glimepiride, and (ii) tablets comprising a combination of 30 mg/4 mg of pioglitazone hydrochloride/glimepiride.

67. By this ANDA filing, Sandoz 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/glimepiride drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Sandoz has indicated that its combination pioglitazone and glimepiride drug products are bioequivalent to Takeda's combination pioglitazone and glimepiride drug products.

68. By its ANDA filing, Sandoz seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' DUETACT® pioglitazone and glimepiride combination drug products prior to the expiration date of the '640 patent.

69. By a Notice Letter dated March 18, 2010, Sandoz informed plaintiffs that Sandoz had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about March 19, 2010, NDA holder, Takeda Global, received the Notice Letter. On or about March 23, 2010, patent owner, TPC, received a duplicate original of the Notice Letter.

70. The Notice Letter, purporting to be Sandoz's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Sandoz's opinion, the '640 patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer of sale of the Sandoz's Pioglitazone HCL/Glimepiride Tablets . . . ."

71. Sandoz's filing of ANDA No. 20-1049 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 or salts thereof and glimepiride before the expiration of the '640 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

72. Sandoz's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and glimepiride drug products will directly infringe at least one of the claims of the '640 patent.

73. Unless Sandoz is enjoined from infringing, contributing to and/or inducing the infringement of the '640 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII

(INDUCEMENT OF INFRINGEMENT OF THE '640 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 20-1049 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 '640 patent, immediately or imminently upon approval of the ANDA.

76. Upon information and belief, Sandoz is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with glimepiride, 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, Sandoz's proposed label for its combination pioglitazone and glimepiride products will instruct patients to take pioglitazone in combination with glimepiride for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Sandoz and to customers of Sandoz. Sandoz will be marketing its pioglitazone and glimepiride combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '640 patent. Sandoz knows or reasonably should know that its proposed conduct will induce infringement of the '640 patent.

78. Upon information and belief, Sandoz's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Sandoz intends to do the same for any approved generic pioglitazone and glimepiride combination drug product, namely Sandoz intends to list its generic product and refer customers to Takeda's product, DUETACT®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and glimepiride drug product to infer that prescribing information for DUETACT®, which includes directions relating to the use of a combination of pioglitazone and glimepiride, also applies to Sandoz's generic combination pioglitazone and glimepiride 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 '640 patent. Plaintiffs have no adequate remedy at law.

COUNT IX

(CONTRIBUTORY INFRINGEMENT OF THE '640 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 the paragraphs above.

82. On information and belief, Sandoz seeks FDA approval of ANDA 20-1049 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and glimepiride combination drug products.

83. On information and belief, approval of ANDA 20-1049 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 '640 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 '640 patent. Plaintiffs have no adequate remedy at law.

COUNT X

(DIRECT INFRINGEMENT OF THE '125 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

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

87. Upon information and belief, defendant Sandoz, filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 20-1049) seeking approval to market (i) tablets comprising a combination of 30 mg/2 mg of pioglitazone hydrochloride/glimepiride, and (ii) tablets comprising a combination of 30 mg/4 mg of pioglitazone hydrochloride/glimepiride.

88. By this ANDA filing, Sandoz 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/glimepiride drug products, immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Sandoz has indicated that its combination pioglitazone and glimepiride drug products are bioequivalent to Takeda's combination pioglitazone and glimepiride drug products.

89. By its ANDA filing, Sandoz seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' DUETACT® pioglitazone and glimepiride combination drug products prior to the expiration date of the '125 patent.

90. By a letter (the "Notice Letter") dated March 18, 2010, Sandoz informed plaintiffs that Sandoz had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about March 19, 2010, NDA holder, Takeda Global, received the Notice Letter. On or about March 23, 2010, patent owner, TPC, received a duplicate original of the Notice Letter.

91. The Notice Letter, purporting to be Sandoz's Notification of Certification under 21 U.S.C.§ 355(j)(2)(B)(iv), alleges that in Sandoz's opinion, the '125 patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz's Pioglitazone HCL/Glimepiride Tablets . . . ."

92. Sandoz's filing of ANDA No. 20-1049 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 or salts thereof and glimepiride before the expiration of the '125 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

93. Sandoz's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and glimepiride drug products will directly infringe at least one of the claims of the '125 patent.

94. Unless Sandoz is enjoined from infringing, contributing to and/or inducing the infringement of the '404 patent, plaintiffs will suffer substantial and irreparable injury. 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 Sandoz's drug products for which it seeks FDA approval or the active ingredients pioglitazone and glimepiride in combination, 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 Sandoz's drug

products or the active ingredients pioglitazone and glimepiride 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 Sandoz's drug products or the active ingredients pioglitazone and glimepiride 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 Sandoz to commercially to make, use, sell, offer to sell or import pioglitazone in combination with glimepiride or any drug product containing pioglitazone in combination with glimepiride 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 the Takeda patents 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 glimepiride, 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
April 29, 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 A. 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) 439-4444