David P. Langlois (DL 2319)
SUTHERLAND ASBILL & BRENNAN LLP
Grace Building
1114 Avenue of the Americas, 40th Floor
New York, New York 10036-7703
Phone: 212-389-5000
Fax: 212-389-5099

Of Counsel:
John L. North
Jeffrey J. Toney
Laura Fahey Fritts
Kristin E. Goran
SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street NE
Atlanta, Georgia 30309-3996
Phone: 404-853-8000
Fax: 404-853-8806

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

IN THE 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,	)	Civil Action No.: 09-cv-4665
v.	)	
Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc.,	)	
Defendants.	)	

TEVA PHARMACEUTICALS USA, INC.'S SUPPLEMENTAL ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIM

Defendants Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA"; collectively, "Teva"), by and through their undersigned attorneys, respond to the numbered paragraphs of the Complaint filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc. (collectively, "Takeda") as follows:

Jurisdiction and Venue

1. Teva admits that this action purports to be an action for patent infringement arising under the patent laws of the United States. Teva further admits that this Court has subject matter jurisdiction. Teva USA does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva Ltd. does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Except as expressly admitted above, Teva denies the allegations in Paragraph 1.

Parties

2. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

3. Teva admits that ACTOS® drug products contain the active ingredient pioglitazone hydrochloride. Teva further admits that ACTOPLUS MET® drug products contain the active ingredients pioglitazone hydrochloride and metformin hydrochloride. Teva is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3, and therefore denies them.

4. Teva admits that Teva USA is incorporated in the state of Delaware and has a place of business in North Wales, Pennsylvania. Teva further admits that ANDA No. 91-155 was filed

under the name of Teva USA. Except as expressly admitted above, Teva denies the allegations in Paragraph 4.

5. Teva admits that Teva Ltd. is a corporation incorporated under the laws of Israel and has its corporate headquarters in Israel. Teva further admits that Teva USA is an indirect wholly owned subsidiary of Teva Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 5.

6. Teva USA does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva Ltd. does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva admits that Teva USA is registered with the N.Y. Department of State, Division of Corporations, to do business as a foreign corporation in New York. Except as expressly admitted above, Teva denies the allegations in Paragraph 6.

The New Drug Applications

7. Upon information and belief, Teva admits the allegations in Paragraph 7.

8. Upon information and belief, Teva admits that the approved indications for ACTOS® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 8.

9. Upon information and belief, Teva admits that the approval letter for ACTOS®, with approved labeling, was issued by the FDA on July 15, 1999. Upon information and belief, Teva further admits that the approved indications for ACTOS® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 9.

10. Upon information and belief, Teva admits the allegations in Paragraph 10.

11. Upon information and belief, Teva admits that the approved indications for ACTOPLUS MET® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 11.

12. Upon information and belief, Teva admits the allegations in Paragraph 12.

The Patents in Suit

13. United States Patent No. 5,965,584 ("the '584 patent") speaks for itself. Teva admits that the '584 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of October 12, 1999 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '584 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '584 patent is attached to the Complaint as Exhibit A. To the extent Paragraph 13 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 13.

14. Upon information and belief, Teva admits that the '584 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '584 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 14.

15. United States Patent No. 6,329,404 ("the '404 patent") speaks for itself. Teva admits that the '404 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of December 11, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '404 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '404 patent is attached to the Complaint as Exhibit B. To the

extent Paragraph 15 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 15.

16. Upon information and belief, Teva admits that the '404 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '404 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 16.

17. United States Patent No. 6,166,043 ("the '043 patent") speaks for itself. Teva admits that the '043 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of December 26, 2000 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '043 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '043 patent is attached to the Complaint as Exhibit C. To the extent Paragraph 17 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 17.

18. Upon information and belief, Teva admits that the '043 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '043 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 18.

19. United States Patent No. 6,172,090 ("the '090 patent") speaks for itself. Teva admits that the '090 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of January 9, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '090 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that

what purports to be a copy of the ‘090 patent is attached to the Complaint as Exhibit D. To the extent Paragraph 19 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 19.

20. Upon information and belief, Teva admits that the ‘090 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the ‘090 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 20.

21. United States Patent No. 6,211,205 (“the ‘205 patent”) speaks for itself. Teva admits that the ‘205 patent, entitled “Pharmaceutical Composition,” lists on its face an issue date of April 3, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the ‘205 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the ‘205 patent is attached to the Complaint as Exhibit E. To the extent Paragraph 21 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 21.

22. Upon information and belief, Teva admits that the ‘205 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the ‘205 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 22.

23. United States Patent No. 6,271,243 (“the ‘243 patent”) speaks for itself. Teva admits that the ‘243 patent, entitled “Pharmaceutical Composition,” lists on its face an issue date of August 7, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the ‘243 patent lists

on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '243 patent is attached to the Complaint as Exhibit F. To the extent Paragraph 23 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 23.

24. Upon information and belief, Teva admits that the '243 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 24.

25. United States Patent No. 6,303,640 ("the '640 patent") speaks for itself. Teva admits that the '640 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of October 16, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '640 patent is attached to the Complaint as Exhibit G. To the extent Paragraph 25 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 25.

26. Upon information and belief, Teva admits that the '640 patent, if valid and enforceable, expires on August 9, 2016. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 26.

27. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 27, and therefore denies them.

28. Upon information and belief, Teva admits that plaintiff TPNA sells pioglitazone-containing drug products under the trade name ACTOS® in the United States. Upon information and belief, Teva further admits that sales of ACTOS® are made pursuant to approval by the FDA of NDA No. 21-073. Except as expressly admitted above, Teva denies the allegations in Paragraph 28.

29. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

30. Upon information and belief, Teva admits that plaintiff TPNA sells drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS MET® in the United States. Upon information and belief, Teva further admits that sales of ACTOPLUS MET® are made pursuant to approval by the FDA of NDA No. 21-842. Except as expressly admitted above, Teva denies the allegations in Paragraph 30.

31. Upon information and belief, Teva admits the allegations in Paragraph 31.

32. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 32, and therefore denies them.

33. Teva denies the allegations in Paragraph 33.

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. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-33.

35. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), 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. Except as expressly admitted above, Teva denies the allegations in Paragraph 35.

36. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 36.

37. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to 15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 37.

38. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 38.

39. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA'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." Except as expressly admitted above, Teva denies the allegations in Paragraph 39.

40. Teva denies the allegations in Paragraph 40.

41. Teva denies the allegations in Paragraph 41.

42. Teva denies the allegations in Paragraph 42.

COUNT II

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

43. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-42.

44. Teva denies the allegations in Paragraph 44.

45. Teva denies the allegations in Paragraph 45.

46. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 46.

47. Teva denies the allegations in Paragraph 47.

48. Teva denies the allegations in Paragraph 48.

49. Teva denies the allegations in Paragraph 49.

COUNT III

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

50. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-49.

51. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 51.

52. Teva denies the allegations in Paragraph 52.

53. Teva denies the allegations in Paragraph 53.

54. Teva denies the allegations in Paragraph 54.

COUNT IV

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

55. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-54.

56. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), 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. Except as expressly admitted above, Teva denies the allegations in Paragraph 56.

57. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 57.

58. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to 15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 58.

59. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 59.

60. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA's opinion,

the '043 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Except as expressly admitted above, Teva denies the allegations in Paragraph 60.

61. Teva denies the allegations in Paragraph 61.

62. Teva denies the allegations in Paragraph 62.

63. Teva denies the allegations in Paragraph 63.

COUNT V

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

64. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-63.

65. Teva denies the allegations in Paragraph 65.

66. Teva denies the allegations in Paragraph 66.

67. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 67.

68. Teva denies the allegations in Paragraph 68.

69. Teva denies the allegations in Paragraph 69.

70. Teva denies the allegations in Paragraph 70.

COUNT VI

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

71. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-70.

72. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 72.

73. Teva denies the allegations in Paragraph 73.

74. Teva denies the allegations in Paragraph 74.

75. Teva denies the allegations in Paragraph 75.

COUNT VII

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

76. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-75.

77. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), 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. Except as expressly admitted above, Teva denies the allegations in Paragraph 77.

78. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 78.

79. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to

15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 79.

80. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 80.

81. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA's opinion, the '090 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Except as expressly admitted above, Teva denies the allegations in Paragraph 81.

82. Teva denies the allegations in Paragraph 82.

83. Teva denies the allegations in Paragraph 83.

84. Teva denies the allegations in Paragraph 84.

COUNT VIII

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

85. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-84.

86. Teva denies the allegations in Paragraph 86.

87. Teva denies the allegations in Paragraph 87.

88. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 88.

89. Teva denies the allegations in Paragraph 89.

90. Teva denies the allegations in Paragraph 90.

91. Teva denies the allegations in Paragraph 91.

COUNT IX

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

92. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-91.

93. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 93.

94. Teva denies the allegations in Paragraph 94.

95. Teva denies the allegations in Paragraph 95.

96. Teva denies the allegations in Paragraph 96.

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. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-96.

98. Teva admits that Teva USA filed ANDA No. 77-210 with the FDA under 21 U.S.C. § 355(j), 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. Except as expressly admitted above, Teva denies the allegations in Paragraph 98.

99. Teva denies the allegations in Paragraph 99.

100. Teva denies the allegations in Paragraph 100.

101. Teva denies the allegations in Paragraph 101.

102. Teva denies the allegations in Paragraph 102.

103. Teva denies the allegations in Paragraph 103.

104. Teva denies the allegations in Paragraph 104.

105. Teva denies the allegations in Paragraph 105.

COUNT XI

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

106. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-105.

107. Teva denies the allegations in Paragraph 107.

108. Teva denies the allegations in Paragraph 108.

109. Teva denies the allegations in Paragraph 109.

110. Teva denies the allegations in Paragraph 110.

111. Teva denies the allegations in Paragraph 111.

112. Teva denies the allegations in Paragraph 112.

113. Teva denies the allegations in Paragraph 113.

COUNT XII

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

114. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-113.

115. Teva denies the allegations in Paragraph 115.

116. Teva denies the allegations in Paragraph 116.

117. Teva denies the allegations in Paragraph 117.

118. Teva denies the allegations in Paragraph 118.

119. Teva denies the allegations in Paragraph 119.

120. Teva denies the allegations in Paragraph 120.

121. Teva denies the allegations in Paragraph 121.

COUNT XIII

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

122. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-121.

123. Teva denies the allegations in Paragraph 123.

124. Teva denies the allegations in Paragraph 124.

125. Teva denies the allegations in Paragraph 125.

126. Teva denies the allegations in Paragraph 126.

127. Teva denies the allegations in Paragraph 127.

128. Teva denies the allegations in Paragraph 128.

129. Teva denies the allegations in Paragraph 129.

COUNT XIV

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

130. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-129.

131. Teva denies the allegations in Paragraph 131.

132. Teva denies the allegations in Paragraph 132.

133. Teva denies the allegations in Paragraph 133.

134. Teva denies the allegations in Paragraph 134.

135. Teva denies the allegations in Paragraph 135.

136. Teva denies the allegations in Paragraph 136.

137. Teva denies the allegations in Paragraph 137.

COUNT XV

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

138. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-137.

139. Teva denies the allegations in Paragraph 139.

140. Teva denies the allegations in Paragraph 140.

141. Teva denies the allegations in Paragraph 141.

142. Teva denies the allegations in Paragraph 142.

143. Teva denies the allegations in Paragraph 143.

144. Teva denies the allegations in Paragraph 144.

145. Teva denies the allegations in Paragraph 145.

COUNT XVI

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

146. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-145.

147. Teva denies the allegations in Paragraph 147.

148. Teva denies the allegations in Paragraph 148.

149. Teva denies the allegations in Paragraph 149.

150. Teva denies the allegations in Paragraph 150.

151. Teva denies the allegations in Paragraph 151.

152. Teva denies the allegations in Paragraph 152.

153. Teva denies the allegations in Paragraph 153.

Teva denies that Takeda is entitled to any relief requested in paragraphs (a) through (g) of its "prayer for relief."

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584 patent.

SECOND AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '404 patent.

THIRD AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '043 patent.

FOURTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '090 patent.

FIFTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '205 patent.

SIXTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '243 patent.

SEVENTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '640 patent.

EIGHTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '584 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

NINTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '404 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

TENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '043 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

ELEVENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '090 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

TWELFTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '205 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '243 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '640 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112. Without limiting the foregoing, upon further information and belief, the claims of the '640 patent are invalid due to nonstatutory double patenting.

FIFTEENTH AFFIRMATIVE DEFENSE

Takeda's claims for injunctive relief are barred because Takeda has an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

Takeda's Complaint fails to state a claim upon which relief can be granted.

WHEREFORE, Teva hereby demands judgment dismissing Takeda's Complaint with prejudice, judgment for costs and fees of suit, and judgment for such other relief as the Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

a) dismissing the Complaint, and each and every claim for relief contained therein, with prejudice;

b) declaring that Teva USA has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584, '404, '043, '090, '205, '243, and '640 patents;

c) declaring that Teva Ltd. has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584, '404, '043, '090, '205, '243, and '640 patents;

d) declaring the claims of the '584, '404, '043, '090, '205, '243, and '640 patents invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112;

e) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Teva its attorneys' fees, costs, and expenses; and

f) granting Teva such other and further relief as this Court deems just and proper.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") hereby asserts the following counterclaim pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 355, as follows:

INTRODUCTION

1. Teva brings this counterclaim under a provision of the 2003 amendments to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C)(ii). Teva seeks an order requiring Takeda to correct certain false, misleading, and/or incorrect information Takeda recently submitted to FDA concerning two patents in connection with the Orange Book listings for the NDA for Takeda's Actos® product. Hatch-Waxman explicitly authorizes the Court to grant the relief Teva seeks in these circumstances. The patent information Takeda recently submitted to FDA caused FDA to change the Orange Book status of two patents, though the changes should not have been made because the patents at issue cannot legally support the new Orange Book listings. Unless the relief Teva requests is granted, FDA approval of Teva's ANDA for a generic version of Actos® likely will be substantially and improperly delayed.

2. On March 15, 2010, FDA changed the Orange Book status of the '584 and the '404 patents in relation to the Actos® NDA. Before March 15, 2010, the listing for Actos® in the Orange Book had contained only method-of-use codes for those patents, and FDA had not treated those patents as having drug product claims that claim Actos®. FDA now treats those patents as

containing both (a) method-of-use claims that claim one of the approved uses of Actos®, and (b) drug product (composition) claims that cover the Actos® drug product.

3. FDA made this change entirely on the basis of information that Takeda submitted to FDA in November 2009 and January 2010. At those times, Takeda submitted information to FDA stating that the patents, which were already listed in the Orange Book for Actos® as containing method-of-use claims, also contain drug product claims as well. Takeda pointedly failed to tell FDA, however, that the drug product claims in those two patents do *not* cover the Actos® drug product. As a result, Takeda's submissions gave the strong – but false – impression that the drug product claims in those patents do cover Actos®. FDA did not separately analyze whether the patents properly claim the Actos® drug product. Instead, acting in a purely ministerial capacity consistent with its policy and practice, FDA deferred entirely to Takeda's submission in that regard.

4. Because FDA (in reliance on Takeda's submissions) now treats the '584 and '404 patents as containing both drug product claims and method-of-use claims that claim Actos®, FDA has stated that an ANDA applicant for a generic version of Actos® must submit a paragraph IV certification to the drug product claims if – as Teva has – it has submitted a section viii statement to the method-of-use claims. Without a paragraph IV certification, FDA now states, an ANDA for a generic version of Actos® cannot be approved.

5. Under both the Hatch-Waxman statute itself and the FDA's implementing regulations, the drug product claims for the '584 patent and the '404 patent do not form a permissible basis for listing those patents in the Orange Book in relation to the Actos® NDA. The drug product claims in those patents could properly be listed in the Orange Book for the Actos® NDA only if those patent claims in fact claimed the Actos® drug product. The patents

unequivocally do not do so. The active ingredient in Actos® tablets is pioglitazone hydrochloride. By contrast, the drug product claims in the patents claim drug products that contain *both* pioglitazone *and* certain additional active ingredients, *not* a drug product that contains pioglitazone as its sole active ingredient. Therefore, those patents do not claim the Actos® drug product as a matter of law. Furthermore, because the drug product claims cannot be properly listed in relation to the Actos® NDA, there is no basis for requiring ANDA applicants for a generic version of Actos® to file a paragraph IV certification to those claims.

6. Teva will be substantially harmed unless Takeda is required to correct or delete the patent information concerning the drug product claims of the '584 patent and the '404 patent in the Orange Book in relation to the Actos® NDA. The consequence of those incorrect listings – and the resulting directive by FDA that ANDA applicants must file paragraph IV certifications – will likely cause a substantial delay of approximately *two years* in FDA's approval for Teva's ANDA, from January 2011 (the expiration date of the drug substance patent covering pioglitazone) to February 2013 (the date on which any 180-day exclusivity would expire if first-filers launch in the August 2002 timeframe evidently specified in their settlements with Takeda). In addition, Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available. By contrast, if Takeda were required to correct or delete the information it previously submitted to FDA, none of these improper delays would occur, and ANDAs for generic versions of Actos® could be approved in the manner and within the time frames that Hatch-Waxman actually contemplates.

7. This Court should enter a mandatory order pursuant to Section 355(j)(5)(C)(ii) requiring Takeda to correct or delete the information submitted to FDA for the Actos® NDA concerning the drug product claims of the two patents at issue. Takeda should be required to

submit information to FDA clarifying that the '584 and '404 patents do *not* contain any drug product claims that claim the drug product approved by the Actos® NDA, and that the *only* claims in the patents that pertain in any way to the Actos® NDA are method-of-use claims. Given FDA's policy and practice, such clarifications by Takeda should lead FDA to correct the Orange Book listings and rescind its requirement that Teva submit paragraph IV notifications, which in turn would allow Teva's ANDA for a generic version of Actos® to be approved in January 2011.

PARTIES

8. Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc., is a Delaware corporation with a principal place of business located in North Wales, Pennsylvania. As relevant to these counterclaims, Teva is the applicant for Teva's Actos® ANDA and is a defendant in this patent infringement action brought by Takeda.

9. The Counterclaim Defendants are Takeda Pharmaceutical Company Limited ("TPC"), Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc. (collectively, "Takeda"). The Takeda entities allege in their claims against Teva that they are, respectively: (a) a Japanese corporation having its headquarters in Osaka, Japan and a principal place of business in Osaka, Japan; (b) a wholly owned subsidiary of Takeda American Holdings, Inc., which is a wholly owned U.S. subsidiary of TPC, having a principal place of business in Deerfield, Illinois and organized under the laws of the State of Delaware; and (c) a wholly owned subsidiary of TPC, having a principal place of business in Lake Forest, Illinois and organized under the laws of the State of Delaware. As relevant to these counterclaims, Takeda is the holder of NDA 21-073 and brought a patent infringement action against Teva Pharmaceuticals USA Inc., asserting patent infringement under certain claims of U.S.

Patent Nos. 5,965,584 and 6,329,404 in connection with Teva's ANDA to sell a generic version of Actos®, which ANDA uses NDA 21-073 as the reference listed drug.

JURISDICTION AND VENUE

10. This counterclaim arises under the Federal Food, Drug, and Cosmetics Act, specifically 21 U.S.C. § 355(j)(5)(C)(ii). Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331 and 1338.

11. Personal jurisdiction is proper over Takeda, as Takeda availed itself of the jurisdiction of this Court by filing the patent infringement action in which these counterclaims are being asserted.

12. Venue is proper in this Court, as the statute authorizing this counterclaim, 21 U.S.C. § 355(j)(5)(C)(ii), provides that the cause of action it creates can only be brought as a counterclaim in this patent infringement action.

FACTUAL BACKGROUND

Requirements for Listing Patent Information in the Orange Book

13. Part of the regulatory structure created by the Hatch-Waxman Act involves a process for identifying and addressing patents that arguably apply to brand and generic drug products. Generally speaking, the regulatory structure requires the holder of an NDA to submit information concerning certain patents to the FDA. FDA incorporates that information into a database called "Approved Drug Products with Therapeutic Equivalence Evaluations," but generally referred to as the "Orange Book." Patent information is organized in the Orange Book by being listed for one or more specific NDAs. Then, when a company seeks to file an ANDA, it must submit certain patent certifications or statements, described more fully below, to each patent that is listed in the Orange Book for the NDA that is the reference listed drug for the ANDA.

Depending on the kind of certification or statement the ANDA applicant files, the NDA holder may or may not be entitled to file certain causes of action and obtain certain stays postponing FDA approval of the ANDA.

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

15. FDA has fleshed out this statutory requirement through implementing regulations. *See generally* 21 C.F.R. § 314.53 (2008). The regulations in place for all relevant times state: "An applicant [who has submitted an NDA] shall submit the required information on the declaration form set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product." 21 C.F.R. 314.53(b) (2008); *accord* 21 C.F.R. 314.53(b) (1999 rev.).

16. In addition, the regulations classify the kinds of patents that could potentially be listed in the Orange Book into three categories: "For purposes of this part, such patents consist of [i] drug substance (active ingredient) patents, [ii] drug product (formulation and composition) patents, and [iii] method-of-use patents." 21 C.F.R. 314.53(b).

17. FDA regulations provide specific instructions setting out the circumstances in which it is, or is not, permissible to list a patent in the Orange Book in relation to a particular NDA. With

respect to drug product claims, the FDA regulations provide: "For patents that claim a drug product, the [NDA] applicant shall submit information only on those patents that claim a drug product, as is defined in [§] 314.3, that is described in the pending or approved [NDA] application." 21 C.F.R. § 314.53(b) (2008); *accord* 21 C.F.R. § 314.53(b) (1999 rev.). Section 314.3 defines "drug product" as "a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3(b). Therefore, the regulations permit an NDA holder to submit a drug product patent only if that patent claims the same finished dosage form product that is described in the NDA. Similarly, FDA reiterated in 2003 in connection with revisions to these regulations that "[t]he drug product (formulation or composition) patents submitted must claim the specific drug product described in the pending or approved NDA." 68 Fed. Reg. 36675, 697 (June 18, 2003).

18. FDA adopted certain changes to the patent listing regulations in 2003. For all relevant times prior to the 2003 amendments, FDA recognized the same three categories of patents: drug substance, drug product, or method of use. Prior to 2003, FDA regulations did not require an NDA holder to specify which patent category – drug substance, drug product, method-of-use, or some combination thereof – provided a basis for listing the patent. Instead, FDA only required a declaration stating: "The undersigned declares that Patent No. ____ covers the formulation, composition, and/or method of use of (*name of drug product*). This product is (*currently approved under section 505 of the Federal Food, Drug, and Cosmetics Act*) [or] (*the subject of this application for which approval is being sought*):". 21 C.F.R. § 314.53(c)(2) (1999) (italics and square brackets in original).

19. Following the 2003 amendments, the applicable FDA regulations require an NDA holder to submit more specific information concerning the nature of the patent. For example, for a patent submitted after the NDA was approved, the regulations now require the NDA holder to specify, among other things: "Information on the drug product (composition/formulation) patent including the following: (1) Whether the patent claims the approved drug product as defined in § 314.3 …." 21 C.F.R. § 314.53(c)(2)(ii)(O)(*1*). This new provision does not change the substantive rule about which patents are eligible for filing. It does, however, require the NDA holder to state explicitly whether, if a patent contains drug product claims, those claims do in fact claim the drug product approved by the NDA.

20. Starting in 2003, FDA also published forms which must be completed by an NDA holder submitting patent information for the Orange Book. *See* 21 C.F.R. § 314.53(c)(1) (2008) ("We will not accept the patent information unless it is complete and submitted on the appropriate forms, FDA Forms 3542 or 3542a"). The appropriate form that an NDA holder must submit to list a new patent to an NDA that has already been approved is Form FDA 3542. Under the category "Drug Product (Composition/Formulation)" in that form, the NDA holder must provide a "yes" or "no" answer to Question 3.1, which asks: "Does the patent claim the approved drug product as defined in 21 CFR 314.3?" The form then states that "FDA will not list the patent in the Orange Book as claiming the drug product if: the answer to question 3.1 is 'No,' ….".

21. There are important regulatory consequences that flow from the distinction between whether a patent is listed in the Orange Book on the basis of containing drug product claims versus method-of-use claims. These include:

(a) If a patent is listed on the basis of a drug product claim, and the ANDA applicant wishes to market its generic product before that patent expires, the ANDA

applicant must file a paragraph IV certification as to that patent, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). If, but only if, a generic applicant files a paragraph IV certification, the patentee and/or NDA holder has the opportunity to file a patent infringement lawsuit that would trigger a 30-month stay of FDA's approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(ii). In addition, if the ANDA applicant submits a paragraph IV certification, but another ANDA applicant for the same product already has done so, the subsequent applicant's ANDA cannot be approved until after the first-filer's 180-day exclusivity period has expired. 21 U.S.C. § 355(j)(5)(B)(iv).

(b) By contrast, if a patent is listed solely on the basis of method-of-use claims, then in certain circumstances an ANDA applicant can file what is known as a "section viii statement" with respect to that patent. 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii). In a section viii statement, the ANDA filer indicates that it is not seeking approval for the particular use covered by the method-of-use patent. When an ANDA applicant files a section viii statement, that statement does not give the NDA holder the right to file a lawsuit that would trigger a 30-month stay. Further, an ANDA that contains only a section viii statement can be approved without regard to whether any other ANDA applicant is entitled to a 180-day exclusivity period.

Therefore, the distinction of whether a patent is properly listed on the basis of drug product claims or on the basis of method-of-use claims can have a significant impact on the timing of FDA approval for an ANDA.

The '584 and '404 Patents

22. Takeda alleges that it is the owner through assignment of U.S. Patent No. 5,965,584 ("the '584 patent") and U.S. Patent No. 6,329,404 ("the '404 patent"). *See* Complaint, ¶¶ 13-16.

23. As Takeda acknowledges in its Complaint, the '584 patent contains two separate categories of patent claims. The first category concerns, in Takeda's words, "a pharmaceutical composition comprising pioglitazone or salts thereof in combination with a biguanide (e.g., metformin) …." The second category concerns, in Takeda's words, "methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin." *See* Complaint, ¶ 13. In other words, the '584 patent contains (a) drug product (composition) claims, and (b) method-of-use claims.

24. The '404 patent is similarly structured. As Takeda acknowledges in its Complaint, the '404 patent contains two separate categories of patent claims. The first category concerns, in Takeda's words, "a pharmaceutical composition comprising pioglitazone or salts thereof in combination with an insulin secretion enhancer (e.g., a sulfonylurea, such as repaglinide or glimepiride) …." The second category concerns, in Takeda's words, "methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer." *See* Complaint ¶ 15. Like the '584 patent, the '404 patent contains (a) drug product claims, and (b) method-of-use claims.

25. No claim in either the '584 patent or the '404 patent claims the drug product pioglitazone alone or the use of pioglitazone alone. The drug substance pioglitazone is covered by a different patent, U.S. Patent No. 4,687,777 (the '777 patent), which expires on January 17, 2011.

Actos®: Pioglitazone HCl Tablets

26. Takeda is the holder of NDA 21-073, which approved the sale of pioglitazone hydrochloride tablets for the improvement of glycemic control in patients with Type 2 diabetes. Takeda sells pioglitazone hydrochloride tablets pursuant to NDA 21-073 under the brand name Actos®.

27. The active ingredient in the drug product approved by NDA 21-073 is pioglitazone hydrochloride. Actos® tablets do not contain any biguanide (such as metformin) or any insulin secretion enhancer (such as repaglinide or glimepiride). NDA 21-073 does not approve the sale of a drug product that combines pioglitazone with a biguanide in a finished dosage form or that combines pioglitazone with an insulin secretion enhancer in a finished dosage form.

28. Takeda does sell a drug product that combines pioglitazone and a biguanide in a single finished dosage form, under the brand name Actoplus Met®. To do so, however, Takeda submitted and received approval for a separate new drug application, NDA 21-842; Actoplus Met® is not sold pursuant to NDA 21-073. Similarly, Takeda sells a drug product that combines pioglitazone with an insulin secretion enhancer (glimepiride), under the brand name Duetact®. Again, however, to do so Takeda submitted and received approval for a separate new drug application, NDA 21-925; Duetact® is not sold pursuant to NDA 21-073.

29. Actos® has two approved uses related to the treatment of diabetes. First, Actos® is approved to be used by itself – as a monotherapy – for improved glycemic control in patients with Type 2 diabetes. Second, and separately, Actos® is approved to be used in combination with a sulfonylurea, metformin, or insulin when diet and the single agent does not result in adequate glycemic control.

30. The method-of-use claims of the '584 patent arguably claim one of the approved uses of Actos®. The '584 patent claims a method of using pioglitazone (the active ingredient in Actos®) in combination with a biguanide, such as metformin, and Actos® is approved for (among other things) use in combination with metformin. Similarly, the method-of-use claims of the '404 patent arguably claim one of the approved uses of Actos®. The'404 patent claims a method of using pioglitazone (the active ingredient in Actos®) with an insulin secretion enhancer such as a sulfonylurea, and Actos® is approved for (among other things) use in combination with a sulfonylurea.

31. The drug product claims in the '584 patent and the '404 patent do not even arguably claim the drug product approved by the Actos® NDA. The '584 patent drug product claims concern a drug product that, in the language of the claims of the patent, either "comprising" or that "consists of" pioglitazone and a biguanide. That language means that the claimed drug product must include, at a minimum, *both* pioglitazone *and* a biguanide. By contrast, the Actos® NDA is limited to a drug product for which pioglitazone is the sole active ingredient. Tellingly, Takeda has listed the drug product claims of the '584 patent in the Orange Book as claiming the drug product Actoplus Met® – the combination product containing both pioglitazone and a biguanide. That listing by Takeda effectively concedes that the '584 drug product claims do not claim the drug product Actos®, which has a materially different composition than does Actoplus Met®. In its Complaint, Takeda alleges that "[t]he '584 patent covers the drug product approved in NDA No. 21-842 [*i.e.*, Actoplus Met®]," *see* Complaint ¶ 13, but does not allege that the '584 patent covers the drug product approved in NDA 21-073, the NDA for Actos. Teva did file a paragraph IV certification to the drug product claims of the '584 patent in connection with its ANDA for a generic version of does Actoplus Met®.

32. Similarly, the '404 patent drug product claims concern a drug product "comprising" pioglitazone and an insulin secretion enhancer. That language means that the claimed drug product must include, at a minimum, *both* pioglitazone *and* an insulin secretion enhancer. By contrast, the Actos® NDA is limited to a drug product for which pioglitazone is the sole active ingredient. Tellingly, Takeda has listed the drug product claims of the '404 patent in the Orange Book as claiming the drug product Duetact® – the combination product containing pioglitazone and an insulin secretion enhancer. That listing by Takeda effectively concedes that the '404 patent drug product claims do not claim the drug product Actos®, which has a materially different composition than does Duetact®.

33. The patentee for the '584 patent and the '404 patent might reasonably be able to assert a claim for patent infringement in certain (though not all) circumstances *under the method-of-use claims* of those patents against someone selling pioglitazone tablets without a license. In no circumstance, however, could the patentee for the '584 patent or the '404 patent reasonably assert a claim for patent infringement *under the drug product claims* of those patents against someone selling pioglitazone tablets without a license. Takeda evidently acknowledges this fact, despite what Takeda told FDA in its recent submissions, because to Teva's knowledge and belief Takeda has not asserted the drug product claims in the '584 or '404 patents against any filer of an ANDA for a generic version of Actos®.

34. The '584 patent and the '404 patent can properly be listed in the Orange Book for the Actos® NDA on the basis of their method-of-use claims. The '584 patent and the '404 patent *cannot* properly be listed in the Orange Book for the Actos® NDA on the basis of their drug product claims.

Takeda's Original Listing of the Patents in the Orange Book

35. On information and belief, FDA approved NDA 21-073 for Actos® on or about July 15, 1999. On that date, neither the '584 patent nor the '404 patent had been issued. The '584 patent issued in October 1999, and the '404 patent issued in December 2001.

36. On information and belief, Takeda submitted the patent declaration to list the '584 patent for the Actos® NDA on November 5, 1999. In that declaration, Takeda stated: "The undersigned declares that Patent No. 5,965,584 covers the formulation, composition, **and/or** method of use of Pioglitazone HCl (AD-4833) Tablets **in combination with a biguanide**." (emphasis added).

37. On information and belief, Takeda submitted the patent declaration to list the '404 patent for the Actos® NDA on January 3, 2002. In that declaration, Takeda stated: "The undersigned declares that **at least one claim** of recently issued US Patent Number 6,329,404 can be reasonably asserted to cover the formulation, composition, **and/or** method of use of Pioglitazone HCl (AD-4833) Tablets." (emphasis added).

38. When listed in the Orange Book to NDA 21-073, those patents were flagged as having a method-of-use code, reflecting the method-of-use claims in the patent. That coding in the Orange Book was consistent with the letter and the spirit of the Orange Book listing requirements, as only the method-of-use claims in those patents provide an arguable basis upon which a claim of patent infringement could reasonably be asserted (in certain circumstances) against a company selling a generic version of Actos®.

39. While the Orange Book did also contain a notation in a footnote indicating as a general matter that the inclusion of method-of-use codes for a patent did not necessarily mean that the patent was not also listed on bases other than method-of-use claims, there were no claims in the

'584 and '404 patents other than method-of-use claims that would form a permissible basis for listing those patents in the Orange Book for NDA 21-073 for Actos®.

Teva's ANDA for Generic Pioglitazone HCl Tablets

40. On or about July 14, 2004, Teva filed ANDA 77-210, seeking approval to manufacture, market, and sell generic pioglitazone hydrochloride tablets (the "Actos® ANDA"). Teva's Actos® ANDA uses NDA 21-073, which approved the sale of Actos® tablets, as the reference listed drug.

41. Teva's Actos® ANDA contains certifications and/or statements to the patents Takeda listed in the Orange Book for NDA 21-073. With respect to the '777 patent, Teva submitted a paragraph III certification, indicating that Teva did not challenge that its product would infringe valid and enforceable claims of the patent, and that FDA should not approve Teva's ANDA until the patent expired. All the remaining patents listed in the Orange Book for NDA 21-073 at the time Teva filed its Actos® ANDA – including the '584 and the '404 patents – were listed with method-of-use codes, and the only claims in those patents that might arguably apply to a generic product that uses NDA 21-073 as the reference listed drug are method-of use claims. Teva filed section viii statements to all those patents indicating that Teva will not include language in the label for its proposed generic version of Actos® that refers to combination use, and thereby that Teva's product will not practice the method-of-use claims of the '584 and the '404 patents.

42. On February 7, 2006, FDA granted tentative approval to Teva's ANDA. FDA noted in the tentative approval letter that Teva had filed a paragraph III certification to the '777 patent and section viii statements as to all the other patents, including the '584 patent and the '404 patent. FDA made no statement or suggestion to Teva in the tentative approval letter that Teva's filings as to the '584 patent and the '404 patent were legally insufficient, or that Takeda had submitted

information to FDA as of that time indicating that the '504 patent or the '404 patent contained drug product claims to which a section viii statement would be insufficient.

43. In May 2009, Takeda filed this patent infringement lawsuit against Teva. In paragraph 1 of the Complaint, Takeda avers: "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." *See* Complaint, ¶ 1. The Complaint alleges several counts of patent infringement against Teva, in relation to more than one ANDA. Count X asserts a claim for patent infringement against Teva under § 271(b) alleging that Teva's ANDA for a generic version of Actos® infringes certain method-of-use claims of the '584 patent. Count XI asserts a claim for patent infringement against Teva under § 271(b) alleging that Teva's ANDA for a generic version of Actos® infringes certain method-of-use claims of the '404 patent. Takeda did not allege in the Complaint that Teva's Actos® ANDA infringes the drug product claims of the '584 or '404 patents.

Takeda's Recent Misrepresentation to the FDA
About the Orange Book Listing of the '584 Patent and the '404 Patent

44. Takeda's recent submissions to FDA concerning the '584 and '404 patents seemingly were prompted by a Citizen Petition filed by Sandoz Inc. ("Sandoz") with FDA on or about August 25, 2009. On information and belief, like Teva, Sandoz has filed an ANDA for approval to sell a generic version of Actos®. Unlike Teva, Sandoz included in its ANDA both section viii statements and paragraph IV certifications to the '584 patent and the '404 patent. In its Citizen Petition, Sandoz asked that the FDA "refrain from granting final approval to any ANDA for a generic version of Actos® tablets … if the ANDA includes a '(viii) statement' … with regard to U.S. Patent No. 5,965,584 (the '584 patent) and/or U.S. Patent No. 6,329,404 (the '404 patent), unless that ANDA also includes a Paragraph IV certification … to the respective patent."

45. On or about October 20, 2009, Teva submitted comments to FDA in response to Sandoz's Citizen Petition. In that letter, Teva stated, among other things, that the drug product claims of the '584 and '404 patents were not and could not be listed in the Orange Book in relation to the NDA for Actos®. Therefore, Teva maintained, there was no legal basis for requiring Teva to submit paragraph IV certifications to those patents.

46. On information and belief, or about November 23, 2009, and apparently in response to Teva's letter of October 20, 2009, Takeda wrote to FDA "to confirm the listing of two patents" in the Orange Book. The two patents Takeda addresses in this letter are the '584 patent and the '404 patent. More specifically, Takeda wrote in relevant part:

> As the sponsor of NDA 21-073, Takeda wishes to confirm for FDA the listing of these two patents, under the terms described in Takeda's original patent submissions.
>
> In addition, because these two patents contain both pharmaceutical composition claims and method-of-use claims, Takeda respectfully requests that FDA direct any companies that have submitted abbreviated new drug applications ("ANDAs") referencing Actos® to submit compete patent certifications to these patents. Under FDA precedent and practice, a section viii statement alone is insufficient when a listed patent includes claims *other* than method-of-use claims. By this letter, and based on the original submission of patent information to the agency, Takeda hereby confirms that the two patents at issue include claims other than method-of-use claims."
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> Because the two patents described above contain both drug product composition and method-of-use claims, Takeda also respectfully requests that FDA contact any ANDA applicants that may have submitted only section viii statements regarding one or both of these patents, and direct the applicants to submit appropriate patent certifications. . . . Until proper certifications have been submitted to the '584 and '404 patents, any ANDAs that lack certifications to the patents should be regarded as ineligible for tentative or final approval.

Nowhere does this letter explain that, while the '584 and '404 patents include drug product claims, those claims do not cover the Actos® drug product.

47. On information and belief, on January 22, 2010, Takeda sent a second letter to FDA, this time referencing the Sandoz Citizen Petition. This letter references Takeda's prior letter of November 2009 and states in relevant part with respect to the '584 and '404 patents:

> As detailed in the [November 2009] letter, Takeda submitted these two patents to FDA in 1999 and 2002, respectively, and characterized them for FDA in the appropriate patent declarations as containing both "Drug product" and "Method of use" claims. Since the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to Actos® under the original declarations, in accordance with 21 C.F.R. § 314.53(d)(2)(ii). For this reason, Takeda requested in its November letter that FDA direct companies that have submitted abbreviated new drug applications referencing Actos® to submit appropriate certifications to the patents. Because the patents include drug product claims, a statement under "section viii" of the relevant provision of the [FDCA] for each patent is, by itself, legally insufficient.

Nowhere does this letter explain that, while the '584 and '404 patents include drug product claims, those claims do not cover the Actos® drug product.

The Misleading and Incorrect Information Submitted by Takeda Caused FDA To Change the Orange Book Status of the '584 Patent and the '404 Patent

48. On March 15, 2010, FDA issued its ruling on the Sandoz Citizen Petition. FDA granted the petition. FDA stated, in relevant part:

> This letter responds to your citizen petition, received on August 25, 2009 (Petition), requesting that [FDA] refrain from granting final approval for any [ANDA] for a generic version of Actos® (pioglitazone hydrochloride (HCl)) tablets … if the ANDA includes a section viii statement … with regard to U.S. Patent No. 5,965,584 (the '584 patent) and/or U.S. Patent No. 6,329,404 (the '404 patent) unless that ANDA also includes a paragraph IV certification … to the respective patent. We have carefully considered the Petition and comments submitted to the docket. For the reasons described below, the Petition is granted.

See FDA-2009-P-0411, Letter dated March 15, 2010 ("FDA Letter"), at 1.

49. In its decision, FDA relied expressly on Takeda's submissions to conclude that the '584 and '404 patents contain drug product claims and that, as a result, paragraph IV certification are required. Among other things, FDA stated:

> FDA's role in listing patents and patent information in the Orange Book is ministerial (see *American Bioscience v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001)). FDA relies on the NDA sponsors to provide an accurate patent submission (consistent with previously applicable regulations regarding patent submissions for patents submitted before August 18, 2008 and on FDA Form 3542 for patents submitted after August 18, 2003). . . .
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> * * *
>
> In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA.

FDA Letter, at 9. FDA did not independently determine that the '584 patent and the '404 patent contain drug product claims that can properly be listed for NDA 21-073. Rather, FDA relied entirely on Takeda's assertions that those patents contain drug product claims.

50. On the basis of Takeda's assertion that the '584 patent and the '404 patent contain drug product claims as well as method-of-use claims, FDA concluded that "FDA will consider any ANDA referencing Actos® that lacks appropriate certifications to the '584 and the '404 patents ineligible for final approval." FDA Letter, at 11. Therefore, as of March 15, 2010, and despite FDA's earlier granting of tentative approval to Teva's Actos® ANDA, FDA now requires that Teva submit a paragraph IV certification to the drug product claims in the '584 and '404 patents if Teva seeks approval of its Actos® ANDA before those patents expire in 2016.

Teva Likely Will Suffer Significant Harm if Takeda is Not Required to Correct or Delete the Information it Submitted to FDA

51. As a direct and proximate cause of Takeda's submission of false, misleading, and/or incorrect patent information to FDA, as alleged above, Teva is likely to suffer significant harm in the form of a substantial delay to the approval of Teva's Actos® ANDA. If Teva is required to file a paragraph IV certification due to the incorrect listings of the '584 and the '404 patents in the Orange Book, Takeda might file a new lawsuit triggering a 30-month stay of approval of Teva's Actos® ANDA. In addition, whether or not Takeda files such a lawsuit, Teva's ANDA could not be approved until after the expiration of any 180-day exclusivity period to which the first-filer(s) of ANDA(s) for generic versions of Actos® may be entitled. Either way, final approval of Teva's Actos® ANDA likely will be delayed substantially beyond the January 2011 date (the expiration of the '777 patent) on which Teva's ANDA otherwise likely would be approved. For example, multiple first-filer ANDA applicants for generic versions of Actos® have announced that they reached settlement agreements with Takeda permitting them to launch their generic version of Actos® in August 2012. If the 180-day exclusivity is not triggered till that date, FDA approval of Teva's Actos® ANDA would not occur until February 2013 – more than two years after the date FDA otherwise likely would grant approval.

52. These harms to Teva would be avoided if Takeda were required to clarify to FDA that the drug product claims in the '584 patent and the '404 patent do not claim the drug product approved by NDA 21-073 and do not form a basis upon which Takeda could reasonably assert a claim of patent infringement with respect to Teva's Actos® ANDA. If Takeda made those correcting submissions to FDA, then FDA would have no further basis for insisting that Teva file a paragraph IV certification to the '584 and the '404 patents. As a result, Teva's Actos® ANDA –

which already has tentative approval – likely would be approved in January 2011 when the '777 patent expires.

COUNTERCLAIM I
(Civil Action to Obtain Patent Certainty Under 21 U.S.C. § 355(j)(5)(C)(ii))

53. Teva repeats and realleges the allegations of paragraphs 1 through 52 of these counterclaims as if set forth in full.

54. Takeda is the holder of NDA 21-073, which authorizes the sale of Actos® in the United States.

55. Teva has submitted an ANDA pursuant to 21 U.S.C. § 355(j) seeking approval for a generic version of Actos®, using NDA 21-073 as the reference listed drug.

56. Teva is the defendant in a patent infringement action brought by Takeda alleging infringement of the '584 patent and the '404 patent in relation to Teva's ANDA for a generic version of Actos®.

57. Takeda has submitted false, misleading, and/or incorrect information to the FDA, pursuant to the provisions of the Hatch-Waxman Act and 21 C.F.R. § 314.53 regarding the submission of patent information, for NDA 21-073 concerning the drug product claims of the '584 patent and the '404 patent. In November 2009 and January 2010, Takeda submitted information to FDA for listing for NDA 21-073 that the '584 patent and the '404 patent contain both method-of-use claims and drug product claims, but Takeda failed to make clear that the drug product claims in those patents do not claim the drug product approved by NDA 21-073 and do not provide a basis upon which Takeda could reasonably assert a claim for patent infringement with respect to an ANDA for a generic version of Actos®.

58. The drug product claims in the '584 patent and the '404 patent do not claim the drug product approved by NDA 21-073.

59. The drug product claims in the '584 patent and the '404 patent cannot properly be listed in the Orange Book as claiming the drug product approved by NDA 21-073 as a matter of law. The '584 patent and the '404 patent can properly be listed in the Orange Book for NDA 21-073 only on the basis of method-of-use claims.

60. FDA relied on Takeda's recent submissions regarding the '584 patent and the '404 patent to declare that, due to the drug product claims in those patents, Teva's Actos® ANDA cannot be approved on the basis of section viii statements to those patents alone.

61. The incorrect information in the Orange Book will cause substantial injury to Teva, and will erect regulatory barriers to the approval of Teva's ANDA for a generic version of Actos® that should not apply. Based on FDA's current position, Teva must submit paragraph IV certifications as to those claims if Teva wishes to seek approval of its Actos® ANDA prior to the expiration of the '584 patent and the '404 patent in 2016. If Teva were required to file a paragraph IV certification, FDA approval of Teva's Actos® ANDA likely would be substantially delayed beyond the date that FDA otherwise likely would approve Teva's Actos® ANDA if Takeda were required to correct or delete the information it previously supplied to FDA and FDA would, as a result, not require the filing of a paragraph IV certification.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

a) requiring Takeda, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii), to correct or delete the patent information Takeda submitted to FDA in reference to NDA 21-073 concerning the drug product claims in the '584 and '404 patent by submitting information to FDA clarifying that the drug product claims in those patents do not claim the drug product approved by NDA 21-073 and

that those drug product claims do not form a basis upon which Takeda could reasonably assert a claim of patent infringement against an ANDA applicant for a generic version of Actos®; and

b) granting Teva such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Teva hereby demands a jury trial on all issues so triable.

Dated: March 30, 2010

/s/ David P. Langlois
David P. Langlois (DL 2319)
SUTHERLAND ASBILL & BRENNAN LLP
Grace Building
1114 Avenue of the Americas, 40th Floor
New York, New York 10036-7703
Phone: 212-389-5000

Of Counsel:
John L. North (admitted *pro hac vice*)
Jeffrey J. Toney (admitted *pro hac vice*)
Laura Fahey Fritts (admitted *pro hac vice*)
Kristin E. Goran (admitted *pro hac vice*)
SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street NE
Atlanta, Georgia 30309-3996
Phone: 404-853-8000

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.