IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO., LTD., Plaintiffs, v. BIOCON LTD. and APOTEX CORP., Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Ltd. (collectively "Plaintiffs" or "Teva") bring this action for patent infringement and declaratory judgment against Defendants Biocon Ltd. and Apotex Corp. ("Apotex") (collectively "Defendants").

NATURE OF THE ACTION

1. This is an action brought by Teva for infringement of United States Patent No. 8,232,250 ("the '250 patent"), United States Patent No. 8,399,413 ("the '413 patent"), United States Patent No. 8,969,302 ("the '302 patent"), and United States Patent No. 9,155,776 ("the '776 patent"). This action arises out of Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 209001 seeking approval from the United States Food and Drug Administration ("FDA") to sell a generic version of COPAXONE® 40 mg/mL injection, Teva's innovative

treatment for patients with relapsing-remitting forms of multiple sclerosis, prior to the expiration of the ’250, ’413, ’302, and ’776 patents.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

3. Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. Teva Neuroscience, Inc. (“Teva Neuroscience”), is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131.

5. Yeda Research and Development Co. Ltd. (“Yeda”) is an Israeli company with its principal place of business is at P.O. Box 95, Rehovot, 76100, Israel.

Defendants

6. Upon information and belief, Biocon Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, India 560100.

7. Upon information and belief, Apotex. Corp. is a corporation organized and existing under the laws of Delaware with its principal place of business at 2400 N. Commerce Parkway, Weston, FL, 33326, and is a subsidiary of Apotex Inc.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

8. This action for patent infringement arises under 35 U.S.C. § 271.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Personal Jurisdiction

Biocon Ltd.

10. Upon information and belief, this Court has personal jurisdiction over Biocon Ltd.

11. Upon information and belief, Biocon Ltd. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, rendering it at home in Delaware.

12. Upon information and belief, Biocon Ltd. has filed ANDAs in the United States and markets at least one generic pharmaceutical product in the State of Delaware, simvastatin.

13. Upon information and belief, Biocon Ltd. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including simvastatin.

14. Upon information and belief, Biocon Ltd., in conjunction with Apotex has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including within the State of Delaware.

15. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

16. Upon information and belief, Biocon Ltd., in conjunction with its authorized U.S. agent Apotex, has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

17. Upon information and belief, Biocon Ltd., in conjunction with Apotex, will market, sell, and offer for sale Defendants' proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

18. Upon information and belief, as a result of Biocon Ltd.'s marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of Delaware, in conjunction with Apotex, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

19. Biocon Ltd. sent a letter, dated March 10, 2016, to Teva, including Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that Biocon Ltd. had filed ANDA No. 209001 seeking approval to market Defendants' Glatiramer Acetate Product ("Defendants' Notice Letter").

20. In the alternative, this Court has personal jurisdiction over Biocon Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Biocon Ltd.'s submission of an ANDA filing. Biocon Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction. Exercising jurisdiction over Biocon Ltd. is consistent with the Constitution and laws of the United States.

21. Upon information and belief, Biocon Pharma Inc. is a step-down subsidiary of Biocon Ltd. and is a corporation organized and existing under the laws of Delaware with its principal place of business at 485 U.S. 1 S., Ste B305, Iselin, NJ 08830.

22. Upon information and belief, Biocon Ltd. has authorized Apotex, a Delaware corporation, to accept service of process with respect to this complaint.

23. Upon information and belief, this Court has personal jurisdiction over Biocon Ltd. for the reasons stated herein, including, *inter alia*, Biocon Ltd.'s activities in the forum, activities

directed at the forum, and significant contacts with the forum, all of which render Biocon Ltd. at home in the forum.

Apotex

24. Upon information and belief, this Court has personal jurisdiction over Apotex.

25. Upon information and belief, Apotex is incorporated in the State of Delaware, rendering it at home in Delaware.

26. Upon information and belief, Apotex has engaged in and maintained systematic and continuous business contacts within the State of Delaware and has purposefully availed itself of the benefits and protections of the laws of Delaware. Apotex has availed itself of this Court by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court's jurisdiction in numerous legal proceedings. *See, e.g., Sanofi-Aventis et al. v. Apotex Inc. et al.*, C.A. No. 07-792-GMS (D. Del.); *Warner Chilcott Co., LLC et al. v. Apotex Inc. et al.*, C.A. No. 14-998-GMS (D. Del.); *R-Tech Ueno, Ltd. v. Apotex Inc.*, C.A. No. 15-592-SLR (D. Del.); *OSI Pharmaceuticals, LLC et al. v. Apotex Inc. et al.*, C.A. No. 15-772-SLR (D. Del.); *Salix Pharmaceuticals, Inc. et al. v. Apotex, Inc. et al*., C.A. No. 15-880-GMS (D. Del.); *Vanda Pharmaceuticals Inc. v. Apotex Inc.*, C.A. No. 15-922-GMS (D. Del.); *Shire Development LLC et al. v. Apotex Inc.*, C.A. No. 15-1045-LPS (D. Del.).

27. Upon information and belief, Apotex markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

28. Upon information and belief, Apotex has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

29. Upon information and belief, Apotex routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, amiodarone hydrochloride, azithromycin, cabergoline, clarithromycin, hydrochlorothiazide/losartan potassium, hydrochlorothiazide/quinapril hydrochloride, losartan potassium, montelukast sodium, mycophenolate mofetil, naratriptan hydrochloride, riluzole, sildenafil citrate, tolterodine tartrate, verapamil hydrochloride, and ziprasidone hydrochloride.

30. Upon information and belief, Apotex has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, amiodarone hydrochloride, azithromycin, cabergoline, clarithromycin, hydrochlorothiazide/losartan potassium, hydrochlorothiazide/quinapril hydrochloride, losartan potassium, montelukast sodium, mycophenolate mofetil, naratriptan hydrochloride, riluzole, sildenafil citrate, tolterodine tartrate, verapamil hydrochloride, and ziprasidone hydrochloride.

31. Upon information and belief, Apotex, in conjunction with Biocon Ltd., has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including within the State of Delaware.

32. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

33. Upon information and belief, Apotex has partnered with Biocon Ltd. to seek FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

34. Upon information and belief, Apotex, in conjunction with Biocon Ltd., will market, sell, and offer for sale Defendants' proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

35. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of Delaware, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

36. Biocon Ltd. sent a letter, dated March 10, 2016, to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that Biocon had filed ANDA No. 209001 seeking approval to market Defendants' Glatiramer Acetate Product ("Defendants' Notice Letter") and identifying Apotex as its authorized U.S. agent.

37. Upon information and belief, this Court has personal jurisdiction over Apotex for the reasons stated herein, including, *inter alia*, Apotex's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Apotex at home in the forum.

The Defendants ANDA

38. Defendants filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® 40 mg/mL product ("Defendants' Glatiramer Acetate Product"), prior to the expiration of '250, '413, '302, and '776 patents.

39. FDA assigned the ANDA for Defendants' Glatiramer Acetate Product the number 209001.

40. Defendants also filed with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '250, '413, '302, and '776 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' Glatiramer Acetate Product ("Defendants' Paragraph IV Certification").

41. Defendants' Notice Letter notified Teva that Defendants had filed ANDA No. 209001 seeking approval to market Defendants' Glatiramer Acetate Product prior to the expiration of the '250, '413, '302, and '776 patents.

42. Teva received Defendants' Notice Letter on or around March 11, 2016.

43. Upon information and belief, both Biocon Ltd. and Apotex submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 209001.

Venue

44. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) and § 1391.

BACKGROUND

The '250 Patent

45. The '250 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was duly and legally issued on July 31, 2012.

46. Ety Klinger is the named inventor of the '250 patent.

47. Yeda is the sole owner by assignment of all rights, title and interest in the '250 patent.

48. Teva Ltd. is the exclusive licensee of the '250 patent.

49. The '250 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

50. A true and correct copy of the '250 patent is attached as Exhibit A.

The ’413 Patent

51. The ’413 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on March 19, 2013.

52. Ety Klinger is the named inventor of the ’413 patent.

53. Yeda is the sole owner by assignment of all rights, title and interest in the ’413 patent.

54. Teva Ltd. is the exclusive licensee of the ’413 patent.

55. The ’413 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

56. A true and correct copy of the ’413 patent is attached as Exhibit B.

The ’302 Patent

57. The ’302 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on March 3, 2015.

58. Ety Klinger is the named inventor of the ’302 patent.

59. Yeda is the sole owner by assignment of all rights, title and interest in the ’302 patent.

60. Teva Ltd. is the exclusive licensee of the ’302 patent.

61. The ’302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

62. A true and correct copy of the ’302 patent is attached as Exhibit C.

The ’776 Patent

63. The ’776 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on October 13, 2015.

64. Ety Klinger is the named inventor of the ’776 patent.

65. Yeda is the sole owner by assignment of all rights, title and interest in the '776 patent.

66. Teva Ltd. is the exclusive licensee of the '776 patent.

67. The '776 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

68. A true and correct copy of the '776 patent is attached as Exhibit D.

Teva's COPAXONE® 40 mg/mL Product

69. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market COPAXONE® 40 mg/ml product.

70. Teva USA is the holder of New Drug Application ("NDA") number 20-622, approved by the United States Food and Drug Administration ("FDA") for the use of glatiramer acetate 40mg/mL three times per week with at least 48 hours between doses, marketed as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

71. Teva's innovative COPAXONE® 40 mg/mL product is supplied as single-dose prefilled syringes that contain 40 mg/ml glatiramer acetate for injection, manufactured by Teva Pharmaceutical Industries Ltd., and marketed and sold in the United States by Teva Neuroscience, Inc.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,232,250 BY DEFENDANTS

72. The allegations of the proceeding paragraphs 1-71 are realleged and incorporated herein by reference.

73. Before filing of this action, the '250 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

74. The use of Defendants' Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '250 patent.

75. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Glatiramer Acetate Product would infringe one or more claims of the '250 patent.

76. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Defendants ANDA to obtain approval for Defendants' Glatiramer Acetate Product with a Paragraph IV Certification before the expiration of the '250 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Glatiramer Acetate Product would infringe, induce, and/or contribute to the infringement of one or more claims of the '250 patent.

77. Upon information and belief, Defendants were aware of the '250 patent when engaging in these knowing and purposeful activities and was aware that filing Defendants' ANDA with Defendants' Paragraph IV Certification with respect to the '250 patent constituted an act of infringement of the '250 patent.

78. Upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

79. Upon information and belief, Defendants plan and intend to, and will, induce and/or contribute to the infringement of one or more claims of the ’250 patent immediately and imminently upon approval of Defendants’ ANDA.

80. Upon information and belief, immediately and imminently upon approval of Defendants’ ANDA, Defendants’ Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the ’250 patent under 35 U.S.C. § 271(a).

81. Upon information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the ’250 patent.

82. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’250 patent under 35 U.S.C. § 271(b) when Defendants’ ANDA is approved, plan and intend to, and will, do so immediately and imminently upon approval.

83. Upon information and belief, Defendants know that Defendants’ Glatiramer Acetate Product is especially made or adapted for use in infringing the ’250 patent and that Defendants’ Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

84. Upon information and belief, Defendants, under 35 U.S.C. § 271(c), plan and intend to, and will, contribute to the infringement of the ’250 patent immediately and imminently upon approval of the Defendants’ ANDA.

85. The foregoing actions by Defendants constitute and/or would constitute infringement of the ’250 patent, active inducement of infringement of the ’250 patent and/or contribution to the infringement by others of the ’250 patent.

86. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’250 patent, actively inducing infringement of the ’250 patent and/or contributing to the infringement by others of the ’250 patent.

87. Teva will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants’ Glatiramer Acetate Product.

88. Defendants’ activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,232,250 BY DEFENDANTS

89. The allegations of the proceeding paragraphs 1-88 are realleged and incorporated herein by reference.

90. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants’ Glatiramer Acetate Product soon after FDA approval of Defendants’ ANDA.

91. Such conduct will lead to direct infringement of one or more claims on the ’250 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the ’250 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the ’250 patent under 35 U.S.C. § 271(c).

92. Upon information and belief, Defendants know that Defendants’ Glatiramer Acetate Product is especially made or adapted for use in infringing the ’250 patent and that Defendants’ Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

93. Upon information and belief, Defendants are without a reasonable basis for believing that they would not be liable for actively inducing infringement of the ’250 patent and/or contributing to the infringement by others of the ’250 patent.

94. Defendants’ infringing patent activity complained of herein is imminent and will begin following FDA approval of Defendants’ ANDA.

95. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the ’250 patent. Defendants’ actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

96. Upon information and belief, Defendants will knowingly and willfully infringe, induce and/or contribute to the infringement of the ’250 patent.

97. Teva will be substantially and irreparably harmed if Defendants are not enjoined from infringing the ’250 patent.

98. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants’ Glatiramer Acetate Product.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,399,413 BY DEFENDANTS

99. The allegations of the proceeding paragraphs 1-98 are realleged and incorporated herein by reference.

100. Before filing of this action, the ’413 patent was listed in the Orange Book with respect to Teva’s COPAXONE® 40 mg/mL product.

101. The use of Defendants’ Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the ’413 patent.

102. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Glatiramer Acetate Product would infringe one or more claims of the '413 patent.

103. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Defendants ANDA to obtain approval for Defendants' Glatiramer Acetate Product with a Paragraph IV Certification before the expiration of the '413 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Glatiramer Acetate Product would infringe, induce, and/or contribute to the infringement of one or more claims of the '413 patent.

104. Upon information and belief, Defendants were aware of the '413 patent when engaging in these knowing and purposeful activities and was aware that filing Defendants' ANDA with Defendants' Paragraph IV Certification with respect to the '413 patent constituted an act of infringement of the '413 patent.

105. Upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

106. Upon information and belief, Defendants plan and intend to, and will, induce and/or contribute to the infringement of one or more claims of the '413 patent immediately and imminently upon approval of Defendants' ANDA.

107. Upon information and belief, immediately and imminently upon approval of Defendants' ANDA, Defendants' Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '413 patent under 35 U.S.C. § 271(a).

108. Upon information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '413 patent.

109. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '413 patent under 35 U.S.C. § 271(b) when Defendants' ANDA is approved, plan and intend to, and will, do so immediately and imminently upon approval.

110. Upon information and belief, Defendants know that Defendants' Glatiramer Acetate Product is especially made or adapted for use in infringing the '413 patent and that Defendants' Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

111. Upon information and belief, Defendants, under 35 U.S.C. § 271(c), plan and intend to, and will, contribute to the infringement of the '413 patent immediately and imminently upon approval of the Defendants' ANDA.

112. The foregoing actions by Defendants constitute and/or would constitute infringement of the '413 patent, active inducement of infringement of the '413 patent and/or contribution to the infringement by others of the '413 patent.

113. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the '413 patent, actively inducing infringement of the '413 patent and/or contributing to the infringement by others of the '413 patent.

114. Teva will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Glatiramer Acetate Product.

115. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,399,413 BY DEFENDANTS

116. The allegations of the proceeding paragraphs 1-115 are realleged and incorporated herein by reference.

117. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Glatiramer Acetate Product soon after FDA approval of Defendants' ANDA.

118. Such conduct will lead to direct infringement of one or more claims on the '413 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '413 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '413 patent under 35 U.S.C. § 271(c).

119. Upon information and belief, Defendants know that Defendants' Glatiramer Acetate Product is especially made or adapted for use in infringing the '413 patent and that Defendants' Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

120. Upon information and belief, Defendants are without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '413 patent and/or contributing to the infringement by others of the '413 patent.

121. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Defendants' ANDA.

122. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the '413 patent. Defendants' actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

123. Upon information and belief, Defendants will knowingly and willfully infringe, induce and/or contribute to the infringement of the '413 patent.

124. Teva will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '413 patent.

125. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Glatiramer Acetate Product.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY DEFENDANTS

126. The allegations of the proceeding paragraphs 1-125 are realleged and incorporated herein by reference.

127. Before filing of this action, the '302 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

128. The use of Defendants' Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '302 patent.

129. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

130. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Defendants ANDA to obtain approval for Defendants' Glatiramer Acetate Product with a Paragraph IV Certification before the expiration of the '302 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Glatiramer Acetate Product would infringe, induce, and/or contribute to the infringement of one or more claims of the '302 patent.

131. Upon information and belief, Defendants were aware of the '302 patent when engaging in these knowing and purposeful activities and was aware that filing Defendants' ANDA with Defendants' Paragraph IV Certification with respect to the '302 patent constituted an act of infringement of the '302 patent.

132. Upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

133. Upon information and belief, Defendants plan and intend to, and will, induce and/or contribute to the infringement of one or more claims of the '302 patent immediately and imminently upon approval of Defendants' ANDA.

134. Upon information and belief, immediately and imminently upon approval of Defendants' ANDA, Defendants' Glatiramer Acetate Product will be administered according to

its labeling and prescribing information causing direct infringement of the claims of the ’302 patent under 35 U.S.C. § 271(a).

135. Upon information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the ’302 patent.

136. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’302 patent under 35 U.S.C. § 271(b) when Defendants’ ANDA is approved, plan and intend to, and will, do so immediately and imminently upon approval.

137. Upon information and belief, Defendants know that Defendants’ Glatiramer Acetate Product is especially made or adapted for use in infringing the ’302 patent and that Defendants’ Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

138. Upon information and belief, Defendants, under 35 U.S.C. § 271(c), plan and intend to, and will, contribute to the infringement of the ’302 patent immediately and imminently upon approval of the Defendants’ ANDA.

139. The foregoing actions by Defendants constitute and/or would constitute infringement of the ’302 patent, active inducement of infringement of the ’302 patent and/or contribution to the infringement by others of the ’302 patent.

140. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’302 patent, actively inducing infringement of the ’302 patent and/or contributing to the infringement by others of the ’302 patent.

141. Teva will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if

Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Glatiramer Acetate Product.

142. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT VI FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,969,302 BY DEFENDANTS

143. The allegations of the proceeding paragraphs 1-142 are realleged and incorporated herein by reference.

144. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Glatiramer Acetate Product soon after FDA approval of Defendants' ANDA.

145. Such conduct will lead to direct infringement of one or more claims on the '302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '302 patent under 35 U.S.C. § 271(c).

146. Upon information and belief, Defendants know that Defendants' Glatiramer Acetate Product is especially made or adapted for use in infringing the '302 patent and that Defendants' Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

147. Upon information and belief, Defendants are without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '302 patent and/or contributing to the infringement by others of the '302 patent.

148. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Defendants' ANDA.

149. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the '302 patent. Defendants' actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

150. Upon information and belief, Defendants will knowingly and willfully infringe, induce and/or contribute to the infringement of the '302 patent.

151. Teva will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '302 patent.

152. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Glatiramer Acetate Product.

COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 9,155,776 BY DEFENDANTS

153. The allegations of the proceeding paragraphs 1-152 are realleged and incorporated herein by reference.

154. Before filing of this action, the '776 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

155. The use of Defendants' Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '776 patent.

156. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Glatiramer Acetate Product would infringe one or more claims of the '776 patent.

157. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Defendants ANDA to obtain approval for Defendants' Glatiramer Acetate Product with a Paragraph IV Certification before the expiration of the '776 patent constitutes an act of

infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Glatiramer Acetate Product would infringe, induce, and/or contribute to the infringement of one or more claims of the '776 patent.

158. Upon information and belief, Defendants were aware of the '776 patent when engaging in these knowing and purposeful activities and was aware that filing Defendants' ANDA with Defendants' Paragraph IV Certification with respect to the '776 patent constituted an act of infringement of the '776 patent.

159. Upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Defendants seek approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Defendants' Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

160. Upon information and belief, Defendants plan and intend to, and will, induce and/or contribute to the infringement of one or more claims of the '776 patent immediately and imminently upon approval of Defendants' ANDA.

161. Upon information and belief, immediately and imminently upon approval of Defendants' ANDA, Defendants' Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '776 patent under 35 U.S.C. § 271(a).

162. Upon information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the ’776 patent.

163. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’776 patent under 35 U.S.C. § 271(b) when Defendants’ ANDA is approved, plan and intend to, and will, do so immediately and imminently upon approval.

164. Upon information and belief, Defendants know that Defendants’ Glatiramer Acetate Product is especially made or adapted for use in infringing the ’776 patent and that Defendants’ Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

165. Upon information and belief, Defendants, under 35 U.S.C. § 271(c), plan and intend to, and will, contribute to the infringement of the ’776 patent immediately and imminently upon approval of the Defendants’ ANDA.

166. The foregoing actions by Defendants constitute and/or would constitute infringement of the ’250 patent, active inducement of infringement of the ’776 patent and/or contribution to the infringement by others of the ’776 patent.

167. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’776 patent, actively inducing infringement of the ’776 patent and/or contributing to the infringement by others of the ’776 patent.

168. Teva will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants’ Glatiramer Acetate Product.

169. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 9,155,776 BY DEFENDANTS

170. The allegations of the proceeding paragraphs 1-169 are realleged and incorporated herein by reference.

171. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Glatiramer Acetate Product soon after FDA approval of Defendants' ANDA.

172. Such conduct will lead to direct infringement of one or more claims on the '776 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '776 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '776 patent under 35 U.S.C. § 271(c).

173. Upon information and belief, Defendants know that Defendants' Glatiramer Acetate Product is especially made or adapted for use in infringing the '776 patent and that Defendants' Glatiramer Acetate Product is not suitable for substantial non-infringing uses.

174. Upon information and belief, Defendants are without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '776 patent and/or contributing to the infringement by others of the '776 patent.

175. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Defendants' ANDA.

176. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the

'776 patent. Defendants' actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

177. Upon information and belief, Defendants will knowingly and willfully infringe, induce and/or contribute to the infringement of the '776 patent.

178. Teva will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '776 patent.

179. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Glatiramer Acetate Product.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

(a) a judgment that the '250 patent is valid and enforceable;

(b) a judgment that the '413 patent is valid and enforceable;

(c) a judgment that the '302 patent is valid and enforceable;

(d) a judgment that the '776 patent is valid and enforceable;

(e) a judgment that the case against Defendants is exceptional and awarding Teva its attorneys' fees under 35 U.S.C. § 285;

(f) an award of Teva's reasonable costs and expenses in this action;

(g) an award of any further and additional relief to Teva as this Court deems just and proper;

(h) a judgment that Defendants' submission of ANDA No. 209001 with a Paragraph IV Certification was an act of infringement of one or more claims of the '250 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of

Defendants' Glatiramer Acetate Product prior to the expiration of the '250 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '250 patent;

(i) a judgment that Defendants' submission of ANDA No. 209001 with a Paragraph IV Certification was an act of infringement of one or more claims of the '413 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Glatiramer Acetate Product prior to the expiration of the '413 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '413 patent;

(j) a judgment that Defendants' submission of ANDA No. 209001 with a Paragraph IV Certification was an act of infringement of one or more claims of the '302 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Glatiramer Acetate Product prior to the expiration of the '302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '302 patent;

(k) a judgment that Defendants' submission of ANDA No. 209001 with a Paragraph IV Certification was an act of infringement of one or more claims of the '776 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Glatiramer Acetate Product prior to the expiration of the '776 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '776 patent;

(l) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Defendants ANDA No. 209001 or any product the use of which infringes the ’250 patent, shall be a date that is not earlier than the expiration of the ’250 patent;

(m) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Defendants ANDA No. 209001 or any product the use of which infringes the ’413 patent, shall be a date that is not earlier than the expiration of the ’413 patent;

(n) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Defendants ANDA No. 209001 or any product the use of which infringes the ’302 patent, shall be a date that is not earlier than the expiration of the ’302 patent;

(o) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Defendants ANDA No. 209001 or any product the use of which infringes the ’776 patent, shall be a date that is not earlier than the expiration of the ’776 patent;

(p) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ Glatiramer Acetate Product, or any product the use of which infringes the ’250 patent, or inducing or contributing to the infringement of the ’250 patent until after the expiration of the ’250 patents;

(q) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ Glatiramer Acetate Product, or any product the use of which infringes the ’413 patent, or inducing or contributing to the infringement of the ’413 patent until after the expiration of the ’413 patents;

(r) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate Product, or any product the use of which infringes the '302 patent, or inducing or contributing to the infringement of the '302 patent until after the expiration of the '302 patents;

(s) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate Product, or any product the use of which infringes the '776 patent, or inducing or contributing to the infringement of the '776 patent until after the expiration of the '776 patents;

(t) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate Product, or any product or compound the use of which infringes the '250 patent, or inducing or contributing to the infringement of the '250 patent, until after the expiration of the '250 patent;

(u) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate Product, or any product or compound the use of which infringes the '413 patent, or inducing or contributing to the infringement of the '413 patent, until after the expiration of the '413 patent;

(v) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate

Product, or any product or compound the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent, until after the expiration of the ’302 patent;

(w) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ Glatiramer Acetate Product, or any product or compound the use of which infringes the ’776 patent, or inducing or contributing to the infringement of the ’776 patent, until after the expiration of the ’776 patent;

(x) an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 209001 before the expiration of the ’250 patent;

(y) an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 209001 before the expiration of the ’413 patent;

(z) an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 209001 before the expiration of the ’302 patent;

(aa) an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 209001 before the expiration of the ’776 patent;

(bb) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ Glatiramer Acetate Product, or any product or compound the use of which infringes the ’250 patent, or the inducement or

contribution of the foregoing, prior to the expiration of the ’250 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

(cc) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ Glatiramer Acetate Product, or any product or compound the use of which infringes the ’413 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’413 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

(dd) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ Glatiramer Acetate Product, or any product or compound the use of which infringes the ’302 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’302 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

(ee) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ Glatiramer Acetate Product, or any product or compound the use of which infringes the ’776 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’776 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

Respectfully submitted,

/s/ Karen E. Keller

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