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,	)	C.A. No. _____
v.	)	
SYNTHON PHARMACEUTICALS INC., SYNTHON B.V., and SYNTHON S.R.O. BLANSKO,	)	
Defendants.	)	

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 Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon s.r.o. Blansko, (collectively "Defendants" or "Synthon").

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 8,232,250 ("the '250 patent") and United States Patent No. 8,399,413 ("the '413 patent"). This action arises out of the filing of an Abbreviated New Drug Application ("ANDA") by Synthon seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions 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 and '413 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 at P.O. Box 95, Rehovot, 76100, Israel.

Synthon

6. Upon information and belief, Synthon Pharmaceuticals Inc. is a corporation organized and existing under the laws of North Carolina with its principal place of business at 1007 Slater Road, Suite 150, Durham, NC 27703.

7. Upon information and belief, Synthon B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Microweg 22, P.O. Box 7071, 6503 CM Nijmegen, The Netherlands.

8. Upon information and belief, Defendant Synthon s.r.o. Blansko is a Czech entity having a principal place of business at Brnenska 32/cp.597, 678 17 Blansko, Czech Republic.

9. Upon information and belief, Defendants Synthon Pharmaceuticals Inc. and Synthon s.r.o. Blansko are sister companies with Synthon Holding B.V. as their ultimate parent company.

JURISDICTION AND VENUE

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

11. 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.

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

13. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon Pharmaceuticals, Inc.

14. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. markets, distributes and/or sells generic drugs within the state of Delaware and throughout the United States.

15. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. 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.

16. Upon information and belief, Synthon routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products, including, *inter alia*, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

17. Upon information and belief, Synthon has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of

Delaware, including, *inter alia*, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

18. Upon information and belief, Defendant Synthon Pharmaceuticals Inc. 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® for sale and use throughout the United States, including the State of Delaware.

19. Teva sells COPAXONE® in the State of Delaware.

20. Upon information and belief, Defendant Synthon Pharmaceuticals Inc. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

21. Upon information and belief, Synthon Pharmaceuticals Inc. will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL in the State of Delaware following FDA approval of that product.

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

23. By letter dated October 8, 2014, Synthon Pharmaceuticals, Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206873 seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents ("Synthon Notice Letter").

24. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon Pharmaceuticals, Inc. for the reasons stated herein, including, *inter alia*, Defendant

Synthon Pharmaceuticals Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which also render Defendant Synthon Pharmaceuticals, Inc. at home in the forum.

25. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon B.V.

26. Upon information and belief, Defendant Synthon B.V. is partnering with Defendant Synthon Pharmaceuticals Inc. to attempt to bring a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) to market in the U.S. *See* http://www.synthon.com/Corporate/News/PressReleases/Synthon-Announces-Filing-of-Glatiramer-Acetate-40-mg-mL-ANDA-Containing-a-Paragraph-IV-Certification, accessed 10/14/14; *see also* "Synthon announces successful outcome of the Phase III GATE study with its generic glatiramer acetate." Business Wire, March 27, 2014.

27. Upon information and belief, Defendant Synthon B.V. collaborated and/or acted in concert with Defendant Synthon Pharmaceuticals Inc. to apply for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

28. Upon information and belief, Defendant Synthon B.V. (through its subsidiary Defendant Synthon Pharmaceuticals, Inc.) markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

29. Upon information and belief, Defendant Synthon B.V. 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.

30. Upon information and belief, Defendant Synthon B.V. has 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® for sale and use throughout the United States, including the State of Delaware. Defendant Synthon B.V. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

31. Upon information and belief, Synthon B.V. caused its agent Synthon Pharmaceuticals Inc. to send the Synthon Notice Letter to Teva, a Delaware corporation.

32. Upon information and belief, as a result of Synthon B.V.'s conduct, Synthon will market, sell, and offer for sale its generic version of COPAXONE® 40 mg/mL in the State of Delaware following FDA approval of that product.

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

34. This Court also has personal jurisdiction over Synthon B.V. under Federal Rule of Civil Procedure 4(k)(2).

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

36. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon s.r.o. Blansko.

37. Upon information and belief, Defendant Synthon s.r.o. Blansko is partnering with Defendant Synthon Pharmaceuticals Inc. to attempt to bring a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) to market in the U.S. *See* http://www.synthon.com/Corporate/News/PressReleases/Synthon-Announces-Filing-of-Glatiramer-Acetate-40-mg-mL-ANDA-Containing-a-Paragraph-IV-Certification, accessed 10/14/14; *see also* "Synthon announces successful outcome of the Phase III GATE study with its generic glatiramer acetate." Business Wire, March 27, 2014.

38. Upon information and belief, Defendant Synthon s.r.o. Blansko collaborated and/or acted in concert with Defendant Synthon Pharmaceuticals Inc. to apply for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

39. Upon information and belief, Defendant Synthon s.r.o. Blansko (through its partner subsidiary Defendant Synthon Pharmaceuticals Inc.) markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

40. Upon information and belief, Defendant Synthon s.r.o. Blansko 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.

41. Upon information and belief, Defendant Synthon s.r.o. Blansko has 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® for sale and use throughout the United States, including the State of Delaware.

Defendant Synthon s.r.o. Blankso has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

42. Upon information and belief, Synthon s.r.o. Blansko caused its agent Synthon Pharmaceuticals Inc. to send the Synthon Notice Letter to Teva, a Delaware corporation.

43. Upon information and belief, as a result of Synthon s.r.o. Blansko's conduct, Synthon will market, sell, and offer for sale its generic version of COPAXONE® 40 mg/mL in the State of Delaware following FDA approval of that product.

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

45. This Court also has personal jurisdiction over Synthon s.r.o. Blansko under Federal Rule of Civil Procedure 4(k)(2).

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

47. Upon information and belief, following any FDA approval of Synthon's ANDA, Defendants Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon s.r.o. Blansko will work in concert with one another to make, use, offer to sell, and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

48. Upon information and belief, Synthon B.V. and Synthon s.r.o. Blansko will manufacture Synthon's proposed generic version of COPAXONE® 40 mg/mL on behalf of Synthon Pharmaceuticals Inc. and Synthon Pharmaceuticals Inc. will act as the agent of Synthon

B.V. and/or Synthon s.r.o. Blansko for sale of that product in the United States, including Delaware.

BACKGROUND

The ’250 Patent

49. The ’250 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on July 31, 2012.

50. Ety Klinger is the named inventor of the ’250 patent.

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

52. Teva Ltd. is the exclusive licensee of the ’250 patent.

53. The ’250 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “the Orange Book” (“Orange Book”), with respect to COPAXONE®.

54. A true and correct copy of the ’250 patent is attached as Exhibit A.

The ’413 Patent

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

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

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

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

59. The ’413 patent is listed in the Orange Book with respect to COPAXONE®.

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

Teva's COPAXONE® Product

61. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market a glatiramer acetate product known as COPAXONE®.

62. Teva USA is the holder of New Drug Application ("NDA") number 02-0622, approved by the United States Food and Drug Administration ("FDA") for the use of glatiramer acetate, marketed as COPAXONE®, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

63. Teva's innovative COPAXONE® 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.

The Synthon ANDA

64. Synthon 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® ("Synthon's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

65. FDA assigned the ANDA for Synthon's Glatiramer Acetate Product the number 206873.

66. Synthon 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 and '413 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Synthon's Glatiramer Acetate Product ("Synthon's Paragraph IV Certification").

67. By letter dated October 8, 2014, Synthon notified Teva that it had filed ANDA No. 206873 seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents ("Synthon Notice Letter").

68. Teva received the Synthon Notice Letter no earlier than October 9, 2014.

69. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Synthon Notice Letter.

70. Upon information and belief, Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon s.r.o. Blansko submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206873.

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

71. The allegations of the proceeding paragraphs 1–70 are realleged and incorporated herein by reference.

72. The use of Synthon's Glatiramer Acetate Product is covered by one or more claims of the '250 patent.

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

74. Under 35 U.S.C. § 271(e)(2)(A), Synthon's submission to FDA of Synthon's ANDA to obtain approval for Synthon's Glatiramer Acetate Product with a Paragraph IV Certification related thereto 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 Synthon's Glatiramer Acetate Product containing glatiramer acetate, would infringe one or more claims of the '250 patent.

75. Synthon was aware of the ’250 patent when engaging in these knowing and purposeful activities and was aware that filing Synthon’s ANDA with Synthon’s Paragraph IV Certification with respect to the ’250 patent constituted an act of infringement of the ’250 patent.

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

77. Upon information and belief, Synthon plans and intends to, and will, infringe the ’250 patent immediately and imminently upon approval of Synthon’s ANDA.

78. Upon information and belief, immediately and imminently upon approval of Synthon’s ANDA, there will be direct infringement of the claims of the ’250 patent under 35 U.S.C. § 271(a).

79. Upon information and belief, Synthon, 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.

80. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the ’250 patent when Synthon’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

81. Upon information and belief, Synthon knows that Synthon’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’250 patent and that Synthon’s

Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Synthon, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '250 patent immediately and imminently upon approval of the Synthon's ANDA.

82. The foregoing actions by Synthon 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.

83. Upon information and belief, Synthon 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.

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

85. Synthon's 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

86. The allegations of the proceeding paragraphs 1–85 are realleged and incorporated herein by reference.

87. Upon information and belief, Synthon plans to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's Glatiramer Acetate Product soon after FDA approval of Synthon's ANDA.

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

89. Synthon’s infringing patent activity complained of herein is imminent and will begin following FDA approval of Synthon’s ANDA.

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

91. Upon information and belief, Synthon will knowingly and willfully infringe the ’250 patent.

92. Teva will be irreparably harmed if Synthon is not enjoined from infringing the ’250 patent.

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

93. The allegations of the proceeding paragraphs 1–92 are realleged and incorporated herein by reference.

94. The use of Synthon’s Glatiramer Acetate Product is covered by one or more claims of the ’413 patent.

95. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Synthon’s Glatiramer Acetate Product would infringe one or more claims of the ’413 patent.

96. Under 35 U.S.C. § 271(e)(2)(A), Synthon’s submission to FDA of Synthon’s ANDA to obtain approval for Synthon’s Glatiramer Acetate Product with a Paragraph IV Certification related thereto 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 Synthon's Glatiramer Acetate Product containing glatiramer acetate, would infringe one or more claims of the '413 patent.

97. Synthon was aware of the '413 patent when engaging in these knowing and purposeful activities and was aware that filing Synthon's ANDA with Synthon's Paragraph IV Certification with respect to the '413 patent constituted an act of infringement of the '413 patent.

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

99. Upon information and belief, Synthon plans and intends to, and will, infringe the '413 patent immediately and imminently upon approval of Synthon's ANDA.

100. Upon information and belief, immediately and imminently upon approval of Synthon's ANDA, there will be direct infringement of the claims of the '413 patent under 35 U.S.C. § 271(a).

101. Upon information and belief, Synthon, 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.

102. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the ’413 patent when Synthon’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

103. Upon information and belief, Synthon knows that Synthon’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’413 patent and that Synthon’s Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Synthon, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the ’413 patent immediately and imminently upon approval of the Synthon’s ANDA.

104. The foregoing actions by Synthon 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.

105. Upon information and belief, Synthon 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.

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

107. Synthon’s 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

108. The allegations of the proceeding paragraphs 1–107 are realleged and incorporated herein by reference.

109. Upon information and belief, Synthon plans to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's Glatiramer Acetate Product soon after FDA approval of Synthon's ANDA.

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

111. Synthon's infringing patent activity complained of herein is imminent and will begin following FDA approval of Synthon's ANDA.

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

113. Upon information and belief, Synthon will knowingly and willfully infringe the '413 patent.

114. Teva will be irreparably harmed if Synthon is not enjoined from infringing the '413 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

(a) a judgment that the '250 and '413 patents are valid and enforceable;

(b) a judgment that Defendants' submission of the ANDA No. 206873, was an act of infringement of one or more claims of the '250 and '413 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Synthon's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '250 and '413 patents;

(c) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Synthon ANDA No. 206873 or any product the use of which infringes the '250 or '413 patents, shall be a date that is not earlier than the expiration of the '250 and '413 patents;

(d) 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 Synthon's Glatiramer Acetate Product, or any product the use of which infringes the '250 or '413 patents, or inducing or contributing to the infringement of the '250 or '413 patents until after the expiration of the '250 and '413 patents;

(e) 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 Synthon's Glatiramer Acetate Product, or any product or compound the use of which infringes the '250 or '413 patents, or inducing or contributing to the infringement of the '250 or '413 patents, until after the expiration of the '250 and '413 patents;

(f) an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Synthon ANDA No. 206873 before the expiration of the ’250 and ’413 patents;

(g) 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 Synthon’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’250 or ’413 patents, or the inducement or contribution of the foregoing, prior to the expiration of the ’250 and ’413 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

(h) a judgment that this is an exceptional case and an award to Teva of its attorneys’ fees under 35 U.S.C. § 285;

(i) an award of Teva’s reasonable costs and expenses in this action; and

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

Respectfully submitted,

/s/ Karen E. Keller

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
Attorneys for Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Ltd.

OF COUNSEL:
David M. Hashmall
Elizabeth J. Holland
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Daryl L. Wiesen
John T. Bennett
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

William G. James
GOODWIN PROCTER LLP
901 New York Ave. NW
Washington, D.C. 20001
(202) 346-4000

Dated: November 18, 2014