UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Case No. 12-cv-00179

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES LTD.,
TEVA NEUROSCIENCE, INC.,

and

YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

SYNTHON PHARMACEUTICALS, INC.,
SYNTHON HOLDING B.V.,
SYNTHON B.V. and SYNTHON S.R.O.,

Defendants.

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co. Ltd. (collectively, "Plaintiffs") bring this action for patent infringement and declaratory judgment against Defendants Synthon Pharmaceuticals, Inc., Synthon Holding B.V., Synthon B.V. and Synthon s.r.o. (collectively, "Defendants").

THE PARTIES

1. 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.

2. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, Petah Tikva, 49131, Israel.

3. 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.

4. Yeda Research and Development Co. Ltd. ("Yeda") markets and commercializes new developments emerging from the laboratories of the Weizmann Institute of Science, and its principal place of business is at P.O. Box 95, Rehovot, 76100, Israel.

5. Upon information and belief, Synthon Pharmaceuticals, Inc. ("Synthon Pharmaceuticals") is a North Carolina corporation with its principal place of business at 9000 Development Drive, Research Triangle Park, North Carolina 27709.

6. Upon information and belief, Synthon Holding B.V. ("Synthon Holding") is a Dutch company with its principal place of business at Microweg 22, P.O. Box 7071, 6503 GN Nijmegen, Netherlands.

7. Upon information and belief, Synthon B.V. is a Dutch company with its principal place of business at Microweg 22, P.O. Box 7071, 6503 GN Nijmegen, Netherlands.

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

9. Upon information and belief, Synthon Holding is the ultimate parent of Defendants Synthon Pharmaceuticals, Synthon B.V. and Synthon s.r.o.

10. Upon information and belief, Synthon Pharmaceuticals is doing business in the State of North Carolina, including in this Judicial District. Upon information and belief, Synthon Pharmaceuticals has engaged in continuous and systematic contacts with the State of North Carolina and purposefully availed itself of this forum by, among other things, making, shipping,

using, offering to sell or selling or causing others to use, offer to sell, or sell pharmaceutical products in the State of North Carolina, including in this Judicial District, and deriving revenue from such activities, and by having previously consented to personal jurisdiction and filed counterclaims in this Judicial District.

11. Upon information and belief, Synthon Holding is doing business in the State of North Carolina, including in this Judicial District. Upon information and belief, Synthon Holding, directly or through its subsidiaries, has engaged in continuous and systematic contacts with the State of North Carolina and purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling or causing others to use, offer to sell, or sell pharmaceutical products in the State of North Carolina, including in this Judicial District, and deriving revenue from such activities, and by having previously consented to personal jurisdiction and filed counterclaims in this Judicial District.

12. Upon information and belief, Synthon B.V. is doing business in the State of North Carolina, including in this Judicial District. Upon information and belief, Synthon B.V. has engaged in continuous and systematic contacts with the State of North Carolina and purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling or causing others to use, offer to sell, or sell pharmaceutical products in the State of North Carolina, including in this Judicial District, and deriving revenue from such activities, and by having previously consented to personal jurisdiction and filed counterclaims in this Judicial District.

13. Upon information and belief, Synthon s.r.o. is doing business in the State of North Carolina, including in this Judicial District. Upon information and belief, Synthon s.r.o. has engaged in continuous and systematic contacts with the State of North Carolina and purposefully

availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling or causing others to use, offer to sell, or sell pharmaceutical products in the State of North Carolina, including in this Judicial District, and deriving revenue from such activities.

JURISDICTION

14. This action for patent infringement arises under 35 U.S.C. § 271(e).

15. This Court has jurisdiction over Counts I-XVI 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.

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

17. This Court has personal jurisdiction over Synthon Pharmaceuticals at least because, upon information and belief, Synthon Pharmaceuticals has a principal place of business in this Judicial District. This Court has personal jurisdiction over Synthon Pharmaceuticals, Synthon Holding, Synthon B.V. and Synthon s.r.o. under the North Carolina long-arm statute, N.C. Gen. Stat. § 1-75.4.

BACKGROUND

The Patents-in-Suit

18. United States Patent No. 7,199,098 ("the '098 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 3, 2007, and expires on May 24, 2014. A true and correct copy of the '098 patent is attached as Exhibit A. Since the date of issue of the '098 patent, Yeda has been and still is the owner of that patent.

19. Teva Ltd. is the exclusive licensee of the '098 patent.

20. United States Patent No. 6,939,539 ("the '539 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the

United States Patent and Trademark Office on September 6, 2005, and expires on May 24, 2014. A true and correct copy of the ‘539 patent is attached as Exhibit B. Since the date of issue of the ‘539 patent, Yeda has been and still is the owner of that patent.

21. Teva Ltd. is the exclusive licensee of the ‘539 patent.

22. United States Patent No. 6,054,430 (“the ‘430 patent”), entitled “Copolymer-1 improvements in compositions of copolymers,” was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 25, 2000, and expires on May 24, 2014. A true and correct copy of the ‘430 patent is attached as Exhibit C. Since the date of issue of the ‘430 patent, Yeda has been and still is the owner of that patent.

23. Teva Ltd. is the exclusive licensee of the ‘430 patent.

24. United States Patent No. 6,620,847 (“the ‘847 patent”), entitled “Copolymer-1 improvements in compositions of copolymers,” was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 16, 2003, and expires on May 24, 2014. A true and correct copy of the ‘847 patent is attached as Exhibit D. Since the date of issue of the ‘847 patent, Yeda has been and still is the owner of that patent.

25. Teva Ltd. is the exclusive licensee of the ‘847 patent.

26. United States Patent No. 5,981,589 (“the ‘589 patent”), entitled “Copolymer-1 improvements in compositions of copolymers,” was duly and legally issued to Yeda by the United States Patent and Trademark Office on November 9, 1999, and expires on May 24, 2014. A true and correct copy of the ‘589 patent is attached as Exhibit E. Since the date of issue of the ‘589 patent, Yeda has been and still is the owner of that patent.

27. Teva Ltd. is the exclusive licensee of the ‘589 patent.

28. United States Patent No. 6,342,476 ("the '476 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on January 29, 2002, and expires on May 24, 2014. A true and correct copy of the '476 patent is attached as Exhibit F. Since the date of issue of the '476 patent, Yeda has been and still is the owner of that patent.

29. Teva Ltd. is the exclusive licensee of the '476 patent.

30. United States Patent No. 6,362,161 ("the '161 patent"), entitled "Copolymer-1 improvements on compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on March 26, 2002, and expires on May 24, 2014. A true and correct copy of the '161 patent is attached as Exhibit G. Since the date of issue of the '161 patent, Yeda has been and still is the owner of that patent.

31. Teva Ltd. is the exclusive licensee of the '161 patent.

32. The '098, '539, '430, '847, '589, '476, and '161 patents (collectively, the "Orange Book Patents") were duly and legally submitted to the United States Food and Drug Administration ("FDA"), and were duly and legally published by the FDA pursuant to 21 U.S.C. § 355(b)(1).

33. United States Patent No. 5,800,808 ("the '808 patent"), entitled "Copolymer-1 Improvements on Compositions of Copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 1, 1998, and expires on September 1, 2015. A true and correct copy of the '808 patent is attached as Exhibit H. Since the date of issue of the '808 patent, Yeda has been and still is the owner of that patent.

34. Teva Ltd. is the exclusive licensee of the '808 patent.

35. United States Patent No. 6,048,898 ("the '898 patent"), entitled "Copolymer-1 Improvements on Compositions of Copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 11, 2000, and expires on May 24, 2014. A true and correct copy of the '898 patent is attached as Exhibit I. Since the date of issue of the '898 patent, Yeda has been and still is the owner of that patent.

36. Teva Ltd. is the exclusive licensee of the '898 patent. Collectively, the '808 and '898 patents are referred to herein as the "Process Patents."

The Copaxone® Drug Product

37. Plaintiffs researched, developed, applied for, obtained approval of and market the glatiramer acetate product known around the world as Copaxone®.

38. Teva USA is the holder of New Drug Application ("NDA") number 02-0622, approved by the FDA for the use of glatiramer acetate, marketed as Copaxone®, for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.

39. Teva Neuroscience markets Copaxone® in the United States.

The Synthon ANDA

40. Upon information and belief, Synthon Pharmaceuticals filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j), to obtain approval for glatiramer acetate injection, 20 mg/mL, 1 mL syringes, purported to be generic to Teva USA's Copaxone® ("Synthon's generic glatiramer acetate product"). Upon information and belief, Synthon Pharmaceuticals filed the ANDA, assigned ANDA No. 203857 ("the Synthon ANDA"), to obtain approval to market Synthon's generic glatiramer acetate product before the expiration of the Orange Book Patents.

41. Upon information and belief, Synthon Pharmaceuticals also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification stating that the claims of the Orange Book Patents are invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of Synthon's generic glatiramer acetate product ("Paragraph IV Certification").

42. Upon information and belief, Synthon Holding, Synthon B.V. and Synthon s.r.o. worked in active concert and participation with Synthon Pharmaceuticals to manufacture Synthon's generic glatiramer acetate product and to prepare the Synthon ANDA.

43. Synthon Pharmaceuticals caused to be sent to Teva USA and Yeda a letter ("the Notice Letter"), dated February 20, 2012, notifying them that Synthon Pharmaceuticals had submitted to the FDA an ANDA for a glatiramer acetate and was providing information to Teva USA and Yeda pursuant to 21 U.S.C. §§ 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95.

COUNT I FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,199,098

44. The allegations of proceeding paragraphs 1-43 are realleged and incorporated herein by reference.

45. Under 35 U.S.C. § 271(e)(2)(A), Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '098 patent constitutes an act of infringement of the '098 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '098 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

46. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the '098 patent when they engaged in

these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the '098 patent constituted an act of infringement of the '098 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the '098 patent under 35 U.S.C. § 271(b) by actively and knowingly aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT II FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,939,539

47. The allegations of paragraphs 1-46 are realleged and incorporated herein by reference.

48. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '539 patent constitutes an act of infringement of the '539 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '539 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

49. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the '539 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the '539 patent constituted an act of infringement of the '539 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the '539 patent under 35 U.S.C. § 271(b) by actively and knowingly

aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT III FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,054,430

50. The allegations of paragraphs 1-49 are realleged and incorporated herein by reference.

51. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '430 patent constitutes an act of infringement of the '430 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '430 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

52. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the '430 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the '430 patent constituted an act of infringement of the '430 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the '430 patent under 35 U.S.C. § 271(b) by actively and knowingly aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT IV FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,620,847

53. The allegations of paragraphs 1-52 are realleged and incorporated herein by reference.

54. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '847 patent constitutes an act of infringement of the '847 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '847 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

55. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the '847 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the '847 patent constituted an act of infringement of the '847 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the '847 patent under 35 U.S.C. § 271(b) by actively and knowingly aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT V FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,981,589

56. The allegations of paragraphs 1-55 are realleged and incorporated herein by reference.

57. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '589 patent constitutes an act of infringement of the '589 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell,

sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '589 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

58. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the '589 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the '589 patent constituted an act of infringement of the '589 patent. Defendants Synthon Holding, Synthon B.V.and Synthon s.r.o. induced the infringement of the '589 patent under 35 U.S.C. § 271(b) by actively and knowingly aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT VI FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,342,476

59. The allegations of paragraphs 1-58 are realleged and incorporated herein by reference.

60. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals' submission to the FDA of the Synthon ANDA to obtain approval for Synthon's generic glatiramer acetate product before the expiration of the '476 patent constitutes an act of infringement of the '476 patent, and if approved, Synthon Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product would infringe one or more claims of the '476 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

61. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA.

Upon information and belief, Defendants were aware of the ‘476 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the ‘476 patent constituted an act of infringement of the ‘476 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the ‘476 patent under 35 U.S.C. § 271(b) by actively and knowingly aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT VII FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,362,161

62. The allegations of paragraphs 1-61 are realleged and incorporated herein by reference.

63. Under 35 U.S.C. § 271(e)(2)(A), Defendant Synthon Pharmaceuticals’ submission to the FDA of the Synthon ANDA to obtain approval for Synthon’s generic glatiramer acetate product before the expiration of the ‘161 patent constitutes an act of infringement of the ‘161 patent, and if approved, Synthon Pharmaceuticals’ commercial manufacture, use, offer to sell, sale or importation of Synthon’s generic glatiramer acetate product would infringe one or more claims of the ‘161 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

64. Upon information and belief, Defendants acted in concert and actively and knowingly assisted with, participated in, encouraged, supported, contributed to, aided and abetted and/or directed the preparation of the Synthon ANDA and its submission to the FDA. Upon information and belief, Defendants were aware of the ‘161 patent when they engaged in these knowing and purposeful activities and were aware that submitting to the FDA the Synthon ANDA with a Paragraph IV Certification with respect to the ‘161 patent constituted an act of infringement of the ‘161 patent. Defendants Synthon Holding, Synthon B.V. and Synthon s.r.o. induced the infringement of the ‘161 patent under 35 U.S.C. § 271(b) by actively and knowingly

aiding and abetting the preparation and submission of the Synthon ANDA and the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 7,199,098

65. The allegations of paragraphs 1-64 are realleged and incorporated herein by reference.

66. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

67. Such conduct will constitute direct infringement of one or more claims of the '098 patent under 35 U.S.C. § 271(a), inducement of infringement of the '098 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '098 patent under 35 U.S.C. § 271(g).

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

69. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '098 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT IX FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,939,539

70. The allegations of paragraphs 1-69 are realleged and incorporated herein by reference.

71. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

72. Such conduct will constitute direct infringement of one or more claims of the '539 patent under 35 U.S.C. § 271(a), inducement of infringement of the '539 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

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

74. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '539 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT X FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,054,430

75. The allegations of paragraphs 1-74 are realleged and incorporated herein by reference.

76. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

77. Such conduct will constitute direct infringement of one or more claims of the '430 patent under 35 U.S.C. § 271(a), inducement of infringement of the '430 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '430 patent under 35 U.S.C. § 271(g).

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

79. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '430 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XI FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,620,847

80. The allegations of paragraphs 1-79 are realleged and incorporated herein by reference.

81. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

82. Such conduct will constitute direct infringement of one or more claims of the '847 patent under 35 U.S.C. § 271(a), inducement of infringement of the '847 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '847 patent under 35 U.S.C. § 271(g).

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

84. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '847 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 5,981,589

85. The allegations of paragraphs 1-84 are realleged and incorporated herein by reference.

86. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

87. Such conduct will constitute direct infringement of one or more claims of the '589 patent under 35 U.S.C. § 271(a), inducement of infringement of the '589 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '589 patent under 35 U.S.C. § 271(g).

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

89. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '589 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,342,476

90. The allegations of paragraphs 1-89 are realleged and incorporated herein by reference.

91. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

92. Such conduct will constitute direct infringement of one or more claims of the ‘476 patent under 35 U.S.C. § 271(a), inducement of infringement of the ‘476 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the ‘476 patent under 35 U.S.C. § 271(g).

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

94. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ‘476 patent. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

COUNT XIV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,362,161

95. The allegations of paragraphs 1-94 are realleged and incorporated herein by reference.

96. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon’s generic glatiramer acetate product soon after FDA approval.

97. Such conduct will constitute direct infringement of one or more claims of the ‘161 patent under 35 U.S.C. § 271(a), inducement of infringement of the ‘161 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the ‘161 patent under 35 U.S.C. § 271(g).

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

99. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '161 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 5,800,808

100. The allegations of paragraphs 1-99 are realleged and incorporated herein by reference.

101. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

102. Such conduct will constitute direct infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a), inducement of infringement of the '808 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '808 patent under 35 U.S.C. § 271(g).

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

104. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '808 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XVI FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,048,898

105. The allegations of paragraphs 1-104 are realleged and incorporated herein by reference.

106. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Synthon's generic glatiramer acetate product soon after FDA approval.

107. Such conduct will constitute direct infringement of one or more claims of the '898 patent under 35 U.S.C. § 271(a), inducement of infringement of the '898 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and infringement of the '898 patent under 35 U.S.C. § 271(g).

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

109. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '808 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plantiffs demand judgment against Defendants as follows:

(a) declaring that the '098 patent is valid and enforceable;

(b) declaring that Defendants have infringed one of more claims of the '098 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '098 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(c) declaring that the '539 patent is valid and enforceable;

(d) declaring that Defendants have infringed one of more claims of the '539 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '539 patent by

the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(e) declaring that the '430 patent is valid and enforceable;

(f) declaring that Defendants have infringed one of more claims of the '430 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '430 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(g) declaring that the '847 patent is valid and enforceable;

(h) declaring that Defendants have infringed one of more claims of the '847 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '847 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(i) declaring that the '589 patent is valid and enforceable;

(j) declaring that Defendants have infringed one of more claims of the '589 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '589 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(k) declaring that the '476 patent is valid and enforceable;

(l) declaring that Defendants have infringed one of more claims of the '476 patent by the filing of the Synthon ANDA and would infringe one or more claims of the '476 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon's generic glatiramer acetate product prior to the expiration of said patent;

(m) declaring that the '161 patent is valid and enforceable;

(n) declaring that Defendants have infringed one of more claims of the ‘161 patent by the filing of the Synthon ANDA and would infringe one or more claims of the ‘161 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon’s generic glatiramer acetate product prior to the expiration of said patent;

(o) declaring that the ‘808 patent is valid and enforceable;

(p) declaring that Defendants would infringe one or more claims of the ‘808 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon’s generic glatiramer acetate product prior to the expiration of said patent;

(q) declaring that the ‘898 patent is valid and enforceable;

(r) declaring that Defendants would infringe one or more claims of the ‘898 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Synthon’s generic glatiramer acetate product prior to the expiration of said patent;

(s) ordering that the effective date of the approval of Synthon’s generic glatiramer acetate product shall not be before the date of expiration of the Orange Book Patents, in accordance with 35 U.S.C. § 271(e)(4)(A);

(t) enjoining Defendants from the commercial manufacture, use, offer for sale, sale or importation of Synthon’s generic glatiramer acetate product, in accordance with 35 U.S.C. § 271(e)(4)(B);

(u) awarding Plaintiffs’ damages or other monetary relief in accordance with 35 U.S.C. § 271(e)(4)(C) to compensate Plaintiffs for any and all commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Synthon’s generic glatiramer acetate product prior to the date of expiration of the Orange Book Patents;

(v) declaring this to be an exceptional case and awarding Plaintiffs attorney fees under 35 U.S.C. §§ 285 and 271(e)(4);

(w) in the event that Synthon Pharmaceuticals obtains final approval for Synthon's generic glatiramer acetate product prior to judgment being entered in this action, enjoining, including preliminarily enjoining, Defendants from the commercial manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramer acetate product in the United States before the date of expiration of the Orange Book Patents and Process Patents, in accordance with 35 U.S.C. § 283;

(x) permanently enjoining Defendants from the manufacture, use, offer to sell, sale or importation of Synthon's generic glatiramir acetate product, in accordance with 35 U.S.C. § 283, prior to expiration of the Orange Book Patents and Process Patents; and

(y) awarding any further and additional relief to Plaintiffs as this Court deems just and proper.

Respectfully submitted,

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