

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC.,

TEVA PHARMACEUTICAL
INDUSTRIES LTD.,

TEVA NEUROSCIENCE, INC.,

and

YEDA RESEARCH AND
DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

SANDOZ, INC.,

SANDOZ INTERNATIONAL GMBH,

NOVARTIS AG,

and

MOMENTA PHARMACEUTICALS, INC.

Defendants.

Civil Action No. 08 CV 7611 (BSJ)(AJP)
ECF Case

FIRST AMENDED COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. ("Plaintiffs"), bring this action for patent infringement and declaratory judgment against Defendants Sandoz, Inc., Sandoz International GmbH, Novartis AG, and Momenta Pharmaceuticals, Inc. ("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, P.O. Box 3190, 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, MO 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, Sandoz, Inc., is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and is a wholly owned subsidiary of Novartis AG.

6. Upon information and belief, Sandoz, Inc., is doing business in the State of New York, including in this Judicial District. Sandoz, Inc., is registered to do business in New York, has designated Corporate Service Company at 80 State Street, Albany, New York, 12207-2543 for receipt of service, and maintains a place of business at 227-15 N. Conduit Avenue, Laurelton, New York 11413. Sandoz, Inc. has engaged in continuous and systematic contacts with the State of New York 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 New York including in this Judicial District and deriving revenue from such activities, and by filing claims and counterclaims in this Judicial District.

7. Upon information and belief, Sandoz International GmbH ("Sandoz International") is a German company with its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany, and is a wholly owned subsidiary of Novartis AG. Upon information and belief, Sandoz International has engaged in continuous and systematic contacts

with the State of New York and purposefully availed itself to this forum by doing business, directly or through its subsidiaries (including Sandoz, Inc.), including, among other things, by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in this Judicial District, and deriving revenue from such activities.

8. Upon information and belief, Novartis AG is a Swiss company with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland. Upon information and belief, Novartis AG has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, directly or through its subsidiaries, including, among other things, by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in this Judicial District and deriving revenue from such activities, and by filing claims in this Judicial District.

9. Upon information and belief, Momenta Pharmaceuticals, Inc., (“Momenta”) is a Delaware corporation with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142. Upon information and belief, Momenta has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, including, among other things, soliciting business in the State of New York, including in this Judicial District.

JURISDICTION

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

11. This Court has jurisdiction over Counts I-XXII 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. This Court has personal jurisdiction over Sandoz, Inc., Sandoz International, Novartis AG, and Momenta under the New York long-arm statute, N.Y.C.P.L.R. § 301, et seq.

BACKGROUND

14. 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 its date of issue, Yeda has been and still is the owner of that patent.

15. Teva Ltd. is the exclusive licensee of the ’098 patent.

16. 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 its date of issue, Yeda has been and still is the owner of that patent.

17. Teva Ltd. is the exclusive licensee of the ’539 patent.

18. 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 its date of issue, Yeda has been and still is the owner of that patent.

19. Teva Ltd. is the exclusive licensee of the ’430 patent.

20. 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 its date of issue, Yeda has been and still is the owner of that patent.

21. Teva Ltd. is the exclusive licensee of the ’847 patent.

22. 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 its date of issue, Yeda has been and still is the owner of the ’589 patent.

23. Teva Ltd. is the exclusive licensee of the ’589 patent.

24. 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 its date of issue, Yeda has been and still is the owner of the ’476 patent.

25. Teva Ltd. is the exclusive licensee of the ’476 patent.

26. 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 its date of issue, Yeda has been and still is the owner of the ’161 patent.

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

28. The '098, '539, '430, '847, '589, '476, and '161 patents (collectively, the "Orange Book Patents") were duly and legally submitted to the FDA, and were duly and legally published by the FDA pursuant to 21 USC § 355(b)(1).

29. United States Patent No. 5,800,808 ("the '808 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 1, 1998, and expires on September 1, 2015. A true and correct copy of the '808 patent is attached as Exhibit H. Since its date of issue, Yeda has been and still is the owner of the '808 patent.

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

31. United States Patent No. 8,048,898 (the "'898 patent") entitled "Copolymer-1 improvements in compositions of copolymers" was duly and legally issued to Yeda by the United State 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 its date of issue, Yeda has been and still is the owner of the '898 patent.

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

33. United States Patent No. 6,514,938 (the "'938 patent") entitled "Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use" was duly and legally issued to Yeda by the United States Patent and Trademark Office on February 4, 2003, and expires on September 24, 2019. A true and correct copy of the '938 patent is attached as Exhibit J. Since its date of issue, Yeda has been and still is the owner of the '938 patent.

34. Teva Ltd. is the exclusive licensee of the '938 patent.

35. United States Patent No. 7,074,580 (“the ’580 patent”) entitled “Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use” was duly and legally issued to Yeda by the United States Patent and Trademark Office on July 11, 2006, and expires on February 22, 2020. A true and correct copy of the ’580 patent is attached as Exhibit K. Since its date of issue, Yeda has been and still is the owner of the ’580 patent.

36. Teva Ltd. is the exclusive licensee of the ’580 patent.

37. United States Patent No. 7,163,802 (“the ’802 patent”) entitled “Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use” was duly and legally issued to Yeda by the United States Patent and Trademark Office on January 16, 2007, and expires on September 24, 2019. A true and correct copy of the ’802 patent is attached as Exhibit L. Since its date of issue, Yeda has been and still is the owner of the ’802 patent.

38. Teva Ltd. is the exclusive licensee of the ’802 patent. (Collectively, the ’938, ’580 and ’802 patents are referred to as the “Marker Patents”)

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

40. Teva USA is the holder of a 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 reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.

41. Upon information and belief, Sandoz, Inc., 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, for injection, 20 mg/mL, 1 mL pre-filled syringes, purported to be generic to Teva USA’s Copaxone® (“Sandoz’s generic glatiramer acetate product”). Upon

information and belief, Sandoz, Inc., filed the ANDA, assigned ANDA No. 90-218 (“the Sandoz, Inc. ANDA”), to obtain approval to market Sandoz’s generic glatiramer acetate product before the expiration of the Orange Book Patents.

42. Upon information and belief, Sandoz, Inc. also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the Orange Book Patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Sandoz’s generic glatiramer acetate product.

43. Upon information and belief, Momenta worked in active concert and participation with Sandoz, Inc. to manufacture Sandoz’s generic glatiramer acetate product and to prepare the Sandoz, Inc. ANDA.

44. Sandoz, Inc., caused to be sent to Teva USA, Teva Ltd., Teva Neuroscience (collectively, “Teva”), and Yeda a letter (“the Notice Letter”), dated July 10, 2008, notifying them that Sandoz, Inc., had filed an ANDA for glatiramer acetate and was providing information to Teva pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Teva USA received the Notice Letter on or about July 14, 2008; Teva Ltd. received the Notice Letter on or about July 22, 2008; Teva Neuroscience received the Notice Letter on or about July 14, 2008; and Yeda received the Notice Letter on or about July 21, 2008.

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

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

46. Under 35 U.S.C. § 271(e)(2)(A), Sandoz, Inc.'s, submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz's generic glatiramer acetate product before the expiration of the '098 patent constitutes an act of infringement of the '098 patent, and if approved, Sandoz, Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz'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.

47. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz, Inc.'s, filing of ANDA No. 90-218 for glatiramer acetate, and in 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

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

49. Under 35 U.S.C. § 271(e)(2)(A), Sandoz, Inc.'s, submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz's generic glatiramer acetate product before the expiration of the '539 patent constitutes an act of infringement of the '539 patent, and if approved, Sandoz, Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz'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.

50. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz, Inc.'s, filing of ANDA No. 90-218 for glatiramer acetate,

and in 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

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

52. Under 35 U.S.C. § 271(e)(2)(A), Sandoz, Inc.'s, submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz's generic glatiramer acetate product before the expiration of the '430 patent constitutes an act of infringement of the '430 patent, and if approved, Sandoz, Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz'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.

53. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz, Inc.'s, filing of ANDA No. 90-218 for glatiramer acetate, and in 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

54. The allegations of paragraphs 1-54 are realleged and incorporated herein by reference.

55. Under 35 U.S.C. § 271(e)(2)(A), Sandoz, Inc.'s, submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz's generic glatiramer acetate product before the expiration of the '847 patent constitutes an act of infringement of the '847 patent, and if approved, Sandoz, Inc.'s commercial manufacture, use, offer to sell, sale, or importation of

Sandoz'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.

56. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz, Inc.'s, filing of ANDA No. 90-218 for glatiramer acetate, and in 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

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

58. Under 35 U.S.C. § 271(e)(2)(A), Sandoz Inc's submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz Inc's generic glatiramer acetate product before the expiration of the '589 patent constitutes an act of infringement of the '589 patent, and if approved, Sandoz Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz Inc'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.

59. Upon information and belief, Sandoz International, Novartis AG, and Momenta have has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s filing of ANDA No. 90-218 for glatiramer acetate, and in 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

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

61. Under 35 U.S.C. § 271(e)(2)(A), Sandoz Inc.'s submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz Inc.'s generic glatiramer acetate product before the expiration of the '476 patent constitutes an act of infringement of the '476 patent, and if approved, Sandoz Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz Inc.'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.

62. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s filing of ANDA No. 90-218 for glatiramer acetate, and in 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

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

64. Under 35 U.S.C. § 271(e)(2)(A), Sandoz Inc.'s submission to the FDA of its ANDA No. 90-218 to obtain approval for Sandoz Inc.'s generic glatiramer acetate product before the expiration of the '161 patent constitutes an act of infringement of the '161 patent, and if approved, Sandoz Inc.'s commercial manufacture, use, offer to sell, sale, or importation of Sandoz Inc.'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.

65. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s filing of ANDA No. 90-218 for glatiramer acetate, and in 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**

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

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

68. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

70. 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**

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

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

73. 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).

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

75. 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**

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

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

78. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

80. 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

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

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

83. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

85. 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**

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

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

88. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

90. 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**

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

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

93. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

95. 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**

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

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

98. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

100. 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**

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

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

103. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

105. 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**

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

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

108. 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), and contributory infringement under 35 U.S.C. § 271(c).

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

110. 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 '898 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XVII FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,514,938

111. The allegations of paragraphs 1-110 are realleged and incorporated herein by reference.

112. Sandoz Inc. infringes and has infringed one or more claims of the '938 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of Sandoz Inc.'s generic glatiramir acetate product.

113. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '938 patent.

COUNT XVIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,514,938

114. The allegations of paragraphs 1-113 are realleged and incorporated herein by reference.

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

116. Such conduct will constitute direct infringement of one or more claims of the '938 patent under 35 U.S.C. § 271(a), inducement of infringement of the '938 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

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

118. 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 '938 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XIX FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,074,580

119. The allegations of paragraphs 1-118 are realleged and incorporated herein by reference.

120. Sandoz Inc. infringes and has infringed one or more claims of the '580 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of Sandoz Inc.'s generic glatiramer acetate product.

121. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '580 patent.

**COUNT XX FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF
UNITED STATES PATENT NO. 7,074,580**

122. The allegations of paragraphs 1-121 are realleged and incorporated herein by reference.

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

124. Such conduct will constitute direct infringement of one or more claims of the '580 patent under 35 U.S.C. § 271(a), inducement of infringement of the '580 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

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

126. 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 '938 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT XXI FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,163,802

127. The allegations of paragraphs 1-126 are realleged and incorporated herein by reference.

128. Sandoz Inc. infringes and has infringed one or more claims of the '802 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of Sandoz Inc.'s generic glatiramer acetate product.

129. Upon information and belief, Sandoz International, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '802 patent.

COUNT XXII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 7,163,802

130. The allegations of paragraphs 1-129 are realleged and incorporated herein by reference.

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

132. Such conduct will constitute direct infringement of one or more claims of the '802 patent under 35 U.S.C. § 271(a), inducement of infringement of the '802 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

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

134. 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 '802 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

- (a) declaring that the '098 patent is valid and enforceable;
- (b) declaring that Defendants have infringed one or more claims of the '098 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '098 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '539 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '539 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '430 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '430 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '847 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '847 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '589 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '589 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '476 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '476 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 or more claims of the '161 patent by the filing of ANDA No. 90-218 and would infringe one or more of the claims of the '161 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 of the claims of the '808 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz'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 of the claims of the '898 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (s) declaring that the '938 patent is valid and enforceable;
- (t) declaring that Defendants have infringed one or more claims of the '938 patent and would infringe one or more of the claims of the '938 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (u) declaring that the '580 patent is valid and enforceable;
- (v) declaring that Defendants have infringed one or more claims of the '580 patent and would infringe one or more of the claims of the '580 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (w) declaring that the '802 patent is valid and enforceable;
- (x) declaring that Defendants have infringed one or more claims of the '802 patent and would infringe one or more of the claims of the '802 patent by the threatened

- acts of importation, manufacture, use, offering to sell and sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (y) ordering that the effective date of the approval of Sandoz's generic glatiramer acetate product shall not be before the date of the last to expire of the Orange Book Patents in accordance with 35 U.S.C. § 271(e)(4)(A);
 - (z) enjoining Defendants from the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic glatiramer acetate product, in accordance with 35 U.S.C. § 271(e)(4)(B);
 - (aa) 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, sale, or importation of Sandoz's generic glatiramer acetate product prior to the expiration of the Orange Book Patents;
 - (bb) declaring this to be an exceptional case and awarding Plaintiffs attorney's fees under 35 U.S.C. §§ 285 and 271(e)(4);
 - (cc) in the event that Sandoz, Inc. obtains final approval for Sandoz'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 Sandoz's generic glatiramer acetate product in the U.S. before the date of expiration of the Orange Book Patents in accordance with 35 U.S.C. § 283;
 - (dd) enjoining Defendants from the manufacture, use, offer to sell, sale or importation of Sandoz's generic glatiramir acetate product, in accordance with 35 U.S.C. § 283, prior to expiration of the Marker Patents.

- (ee) enjoining Sandoz, Inc. from the resubmission of ANDA No. 90-218, or any other ANDA referencing NDA 02-0622 containing data obtained by methods which infringed any of the Marker Patents, for a time sufficient to return the parties to the status quo before infringement.
- (ff) awarding Plaintiffs damages or other monetary relief in accordance with 35 U.S.C. § 284 to compensate plaintiffs for any and all manufacture, use, offer to sell, sale, or importation of Sandoz's generic glatiramer acetate product prior to the expiration of the Marker Patents;
- (gg) ordering Sandoz, Inc. to withdraw its ANDA No. 90-218;
- (hh) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Dated: 11/9/2009

Respectfully submitted,

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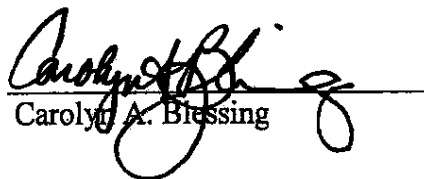
CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2009, I caused copies of the foregoing *First Amended Complaint* to be served on the following counsel of record for defendants Sandoz Inc. and Momenta Pharmaceuticals, Inc. by email:

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