

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

TEVA PHARMACEUTICALS USA, INC.,

TEVA PHARMACEUTICAL
INDUSTRIES LTD.,

TEVA NEUROSCIENCE, INC.,

and

YEDA RESEARCH AND
DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

MYLAN INC.,

and

NATCO PHARMA LTD.

Defendants.

Civil Action No. _____

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 Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”), Mylan Inc., and Natco Pharma Ltd. (“Natco”) (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, 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, Mylan Pharmaceuticals is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

6. Upon information and belief, Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

7. Upon information and belief, Natco is an Indian company with its principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 033, India.

8. Upon information and belief, Mylan Pharmaceuticals is doing business in the State of West Virginia, including in this Judicial District. Mylan Pharmaceuticals is a corporation registered and doing business under the laws of the State of West Virginia, has designated Corporation Service Company, 209 West Washington St., Charleston, WV 25302, for receipt of service, has its principle place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505, and maintains a registered office at P.O. Box 4310, Morgantown, WV 26505. Mylan Pharmaceuticals has engaged in continuous and systematic contacts with the State of West Virginia 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 West Virginia including in this Judicial District and deriving revenue from such activities, and by filing claims and counterclaims in this Judicial District.

9. Upon information and belief, Mylan Inc. is doing business in the State of West Virginia, including in this Judicial District. Mylan Inc., directly or through its subsidiaries, has engaged in continuous and systematic contacts with the State of West Virginia 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 West Virginia including in this Judicial District and deriving revenue from such activities, and by filing claims and counterclaims in this Judicial District.

10. Upon information and belief, Natco is doing business in the State of West Virginia, including in this Judicial District. Natco has engaged in continuous and systematic contacts with the State of West Virginia 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 West Virginia including in this Judicial District and deriving revenue from such activities, and by filing counterclaims in this Judicial District.

JURISDICTION

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

12. This Court has jurisdiction over Counts I-XIV 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.

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

14. This Court has personal jurisdiction over Mylan Pharmaceuticals, by virtue of the fact that it is incorporated in the State of West Virginia and maintains its principle place of business in the State of West Virginia.

15. This Court has personal jurisdiction over Mylan Inc., and Natco under the West Virginia long-arm statute, W. Va. Code § 56-3-33.

BACKGROUND

16. 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 the ’098 patent.

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

18. 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 the ’539 patent.

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

20. 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 the ’430 patent.

21. Teva Ltd. is the exclusive licensee of the '430 patent.

22. 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 the '847 patent.

23. Teva Ltd. is the exclusive licensee of the '847 patent.

24. 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.

25. Teva Ltd. is the exclusive licensee of the '589 patent.

26. 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.

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

28. 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.

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

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

31. 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 reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.

32. Upon information and belief, Mylan 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® ("Mylan's generic glatiramer acetate product"). Upon information and belief, Mylan Pharmaceuticals filed the ANDA, assigned ANDA No. 91-646 ("the Mylan ANDA"), to obtain approval to market Mylan's generic glatiramer acetate product before the expiration of the '098, '539, '430, '847, '589, '476, and '161 patents ("the patents in suit").

33. Upon information and belief, Mylan Pharmaceuticals 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 patents in suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan's generic glatiramer acetate product.

34. Upon information and belief, Natco worked in active concert and participation with Mylan Pharmaceuticals to manufacture Mylan's generic glatiramer acetate product and to

prepare the Mylan ANDA. Upon information and belief, Natco and Mylan Inc. have signed an agreement under which Mylan will market and distribute glatiramer acetate made by Natco (see e.g., http://www.natcopharma.co.in/collaborates_mylan.htm).

35. Mylan Pharmaceuticals caused to be sent to Teva USA, Teva Ltd., Teva Neuroscience (collectively, “Teva”), and Yeda a letter (“the Notice Letter”), dated September 16, 2009, notifying them that Mylan Pharmaceuticals had filed an ANDA for glatiramer acetate and was providing information to Teva pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

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

36. The allegations of proceeding paragraphs 1-34 are realleged and incorporated herein by reference.

37. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals’ submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan’s generic glatiramer acetate product before the expiration of the ’098 patent constitutes an act of infringement of the ’098 patent, and if approved, Mylan Pharmaceuticals’ commercial manufacture, use, offer to sell, sale, or importation of Mylan’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.

38. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals’ filing of ANDA No. 91-646 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

39. The allegations of paragraphs 1-37 are realleged and incorporated herein by reference.

40. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '539 patent constitutes an act of infringement of the '539 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

41. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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

42. The allegations of paragraphs 1-40 are realleged and incorporated herein by reference.

43. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '430 patent constitutes an act of infringement of the '430 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

44. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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

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

46. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '847 patent constitutes an act of infringement of the '847 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

47. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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

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

49. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '589 patent constitutes an act of infringement of the '589 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

50. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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

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

52. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '476 patent constitutes an act of infringement of the '476 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

53. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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

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

55. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '161 patent constitutes an act of infringement of the '161 patent, and

if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan'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.

56. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 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**

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

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

59. 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).

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

61. 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**

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

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

64. 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).

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

66. 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**

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

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

69. 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).

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

71. 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

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

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

74. 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).

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

76. 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**

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

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

79. 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).

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

81. 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**

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

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

84. 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).

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

86. 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

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

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

89. 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).

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

91. 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.

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. 91-646 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 Mylan'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. 91-646 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 Mylan'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. 91-646 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 Mylan'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. 91-646 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 Mylan'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. 91-646 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 Mylan'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. 91-646 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 Mylan'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. 91-646 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 Mylan's generic glatiramer acetate product prior to the expiration of said patent;
- (o) ordering that the effective date of the approval of Mylan's generic glatiramer acetate product shall not be before the date of expiration of the patents in suit, in accordance with 35 U.S.C. § 271(e)(4)(A);
- (p) enjoining Defendants from the commercial manufacture, use, offer to sell, sale, or importation of Mylan's generic glatiramer acetate product, in accordance with 35 U.S.C. § 271(e)(4)(B);
- (q) 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 Mylan's generic glatiramer acetate product prior to the expiration of the patents in suit;
- (r) declaring this to be an exceptional case and awarding Plaintiffs attorney's fees under 35 U.S.C. §§ 285 and 271(e)(4);
- (s) in the event that Mylan Pharmaceuticals obtains final approval for Mylan'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 Mylan's generic glatiramer acetate product in the U.S. before the date of expiration of the patents in suit in accordance with 35 U.S.C. § 283; and

(t) Awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Dated: November 4, 2009

Respectfully submitted,

By: /s/ John Porco
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