IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO., LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN PHARMACEUTICALS INC., MYLAN INC. and NATCO PHARMA LTD.,	)	
Defendants.	)	

COMPLAINT

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

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 8,232,250 ("the '250 patent") and United States Patent No. 8,399,413 ("the '413 patent"). This action arises out of the filing of an Abbreviated New Drug Application ("ANDA") by Mylan seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of COPAXONE® 40 mg/mL injection, Teva's innovative treatment for patients with

relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '250 and '413 patents.

THE PARTIES

Teva

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

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

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

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

Mylan

6. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505.

7. Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc.

8. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

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

JURISDICTION AND VENUE

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

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

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

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

14. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. has availed itself of this forum by bringing a civil action in this forum. *See, e.g., Mylan Pharmaceuticals Inc. et al. v. Eurand Inc. et al.*, C.A. No. 10-00306 (D. Del.); *Mylan Pharmaceuticals Inc. et al. v. Kremers Urban Development Co.*, C.A. No. 02-01628 (D. Del.); *Mylan Pharmaceuticals Inc. et al. v. Galderma Laboratories Inc. et al.*, C.A. No. 10-00892 (D. Del.); *DuPont Merck Pharmaceutical Co. et al. v. Bristol-Myers Squibb Co. et al.*, C.A. No. 95-00290 (D. Del.).

15. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is registered to conduct business with the State of Delaware and maintains as a registered agent Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

16. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is registered pursuant to Del. Code Ann. Tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware.

17. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses from the Delaware Board of Pharmacy.

18. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

19. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

20. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE®, for sale and use throughout the United States, including the State of Delaware.

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

22. Upon information and belief, this Court also has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. because it previously has been sued in this district without challenging this Court's assertion of personal jurisdiction over it and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g.*, *Alcon Research Ltd. v. Mylan Inc. et al.*, C.A. No. 13-01332 (D. Del.); *UCB Inc. et al. v. Mylan Inc. et al.*, C.A. No. 13-01214 (D. Del.); *Forest Laboratories Inc. et al v. Mylan Inc. et al.*, C.A. No. 13-01605 (D. Del.).

23. Upon information and belief, Defendant Mylan Pharmaceuticals Inc.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

24. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. consented to jurisdiction in Delaware by registering to conduct business with the State of Delaware and maintaining a registered agent in Delaware.

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

26. Upon information and belief, this Court has personal jurisdiction over Defendant Mylan Inc.

27. Upon information and belief, Defendant Mylan Inc. has availed itself of this forum by bringing a civil action in this forum. *See, e.g.*, *Mylan Pharmaceuticals Inc. et al. v. Eurand Inc. et al.*, C.A. No. 10-00306 (D. Del.); *Mylan Pharmaceuticals Inc. et al. v. Kremers Urban Development Co.*, C.A. No. 02-01628 (D. Del.); *Mylan Pharmaceuticals Inc. et al. v. Galderma Laboratories Inc. et al.*, C.A. No. 10-00892 (D. Del.); *DuPont Merck Pharmaceutical Co. et al. v. Bristol-Myers Squibb Co. et al.*, C.A. No. 95-00290 (D. Del.).

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

29. Upon information and belief, Defendant Mylan Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

30. Upon information and belief, Defendant Mylan Inc. collaborated and/or acted in concert with Defendants Mylan Pharmaceuticals Inc. and Natco Pharma Ltd. to apply for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

31. Upon information and belief, Defendant Mylan Inc. is partnering with Defendant Natco Pharma Ltd. to attempt to bring a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) to market in the U.S. *See* http://natcopharma.co.in/index.php/news-for-dump/185-news90 (accessed 10/02/14); *see also* Natco Pharma Ltd.'s 31st Annual Report 2013-2014 at 26.

32. Upon information and belief, Defendant Mylan Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE®, for sale and use throughout the United States, including the State of Delaware.

33. Upon information and belief, this Court also has personal jurisdiction over Defendant Mylan Inc. because it previously has been sued in this district without challenging this Court's assertion of personal jurisdiction over it and has availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Alcon Research Ltd. v. Mylan Inc. et al.*, C.A. No. 13-01332 (D. Del.); *UCB Inc. et al. v. Mylan Inc. et al.*, C.A. No. 13-01214 (D. Del.); *Forest Laboratories Inc. et al v. Mylan Inc. et al.*, C.A. No. 13-01605 (D. Del.).

34. Upon information and belief, Defendant Mylan Inc.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

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

36. Upon information and belief, this Court has personal jurisdiction over Defendant Natco Pharma Ltd.

37. Upon information and belief, Defendant Natco Pharma Ltd. is partnering with Defendant Mylan Inc. to attempt to bring a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) to market in the U.S. *See* http://natcopharma.co.in/index.php/news-for-dump/185-news90 (accessed 10/02/14); *see also* Natco Pharma Ltd.'s 31st Annual Report 2013-2014 at 26.

38. Upon information and belief, Defendant Natco Pharma Ltd. is in the business of, among other things, manufacturing and marketing pharmaceutical substances and finished dosage forms for Indian, U.S. and other international markets.

39. Upon information and belief, Defendant Natco Pharma Ltd. manufactures and formulates drugs that are imported into the United States for distribution and sale throughout the United States and within the State of Delaware.

40. Upon information and belief, Defendant Natco Pharma Inc., is a wholly owned subsidiary of Natco Pharma Ltd. *See* Natco Pharma Ltd.'s 31st Annual Report 2013-2014.

41. Upon information and belief, Natco Pharma Inc. is a corporation organized and existing under the laws of Delaware with its principle place of business at 297 Mine Bank Road, Wellsville, PA 17365.

42. Upon information and belief, Defendant Natco Pharma Ltd. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, including through its wholly owned subsidiary Natco Pharma Inc., a Delaware company, by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Natco pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

43. Upon information and belief, Defendant Natco Pharma Ltd. collaborated and/or acted in concert with Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. to apply for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

44. Upon information and belief, following any FDA approval of Mylan's ANDA, Defendants Mylan Pharmaceuticals Inc., Mylan Inc. and Natco Pharma Ltd. will work in concert with one another to make, use, offer to sell, and/or sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

45. Upon information and belief, Defendant Natco Pharma Ltd. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE®, for sale and use throughout the United States, including the State of Delaware.

46. Upon information and belief, this Court also has personal jurisdiction over Defendant Natco Pharma Ltd. because it previously has been sued in this district without challenging this Court's assertion of personal jurisdiction over it and has availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See*,

e.g., *Cephalon Inc. v. Breckenridge Pharmaceutical Inc. et al.*, C.A. No. 14-00671 (D. Del.); *Cephalon Inc. et al. v. Breckenridge Pharmaceutical Inc. et al.*, C.A. No. 11-01070 (D. Del.).

47. Upon information and belief, Defendant Natco Pharma Ltd.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

48. Upon information and belief, this Court also has personal jurisdiction over Natco Pharma Ltd. under Federal Rule of Civil Procedure 4(k)(2).

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

BACKGROUND

The '250 Patent

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

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

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

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

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

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

The ’413 Patent

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

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

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

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

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

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

Teva’s COPAXONE® Product

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

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

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

The Mylan ANDA

65. Mylan filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate

injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® ("Mylan's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

66. FDA assigned the ANDA for Mylan's Glatiramer Acetate Product the number 206936.

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

68. By letter dated August 28, 2014, Mylan notified Teva that it had filed ANDA No. 206936 seeking approval to market Mylan's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents ("Mylan Notice Letter").

69. Teva received the Mylan Notice Letter no earlier than August 28, 2014.

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

71. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., and Natco Pharma Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206936.

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

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

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

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

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

76. Mylan was aware of the '250 patent when engaging in these knowing and purposeful activities and was aware that filing Mylan's ANDA with Mylan's Paragraph IV Certifications with respect to the '250 patent constituted an act of infringement of the '250 patent.

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

78. Upon information and belief, Mylan plans and intends to, and will, infringe the '250 patent immediately and imminently upon approval of Mylan's ANDA.

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

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

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

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

83. The foregoing actions by Mylan constitute and/or would constitute infringement of the '250 patent, active inducement of infringement of the '250 patent and/or contribution to the infringement by others of the '250 patent.

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

85. Teva will be substantially and irreparably harmed by Mylan's infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Mylan is

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

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

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

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

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

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

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

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

92. Upon information and belief, Mylan will knowingly and willfully infringe the '250 patent.

93. Teva will be irreparably harmed if Mylan is not enjoined from infringing the '250 patent.

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

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

95. The use of Mylan's Glatiramer Acetate Product is covered by one or more claims of the '413 patent.

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

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

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

99. Upon information and belief, Mylan seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Mylan's Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Mylan seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Mylan's Glatiramer Acetate Product,

which will be indicated for administration three times per week with at least 48 hours between every injection.

100. Upon information and belief, Mylan plans and intends to, and will, infringe the ’413 patent immediately and imminently upon approval of Mylan’s ANDA.

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

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

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

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

105. The foregoing actions by Mylan constitute and/or would constitute infringement of the ’413 patent, active inducement of infringement of the ’413 patent and/or contribution to the infringement by others of the ’413 patent.

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

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

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

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

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

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

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

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

113. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Mylan as to liability for the infringement of the ’413

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

114. Upon information and belief, Mylan will knowingly and willfully infringe the '413 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

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

(b) a judgment that Defendants' submission of the ANDA No. 206936, was an act of infringement of one or more claims of the '250 and '413 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Mylan's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '250 and '413 patents;

(c) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Mylan ANDA No. 206936 or any product the use of which infringes the '250 or '413 patents, shall be a date that is not earlier than the expiration of the '250 and '413 patents;

(d) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Mylan's Glatiramer Acetate Product, or any product the use of which infringes the '250 or '413 patents, or inducing or

contributing to the infringement of the ’250 or ’413 patents until after the expiration of the ’250 and ’413 patents;

(e) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Mylan’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’250 or ’413 patents, or inducing or contributing to the infringement of the ’250 or ’413 patents, until after the expiration of the ’250 and ’413 patents;

(f) an Order enjoining Defendants and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 206936 before the expiration of the ’250 and ’413 patents;

(g) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Mylan’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’250 or ’413 patents, or the inducement or contribution of the foregoing, prior to the expiration of the ’250 and ’413 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

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

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

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

/s/ Karen E. Keller

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