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. _____
DOCTOR REDDY'S LABORATORIES, LTD., DOCTOR REDDY'S LABORATORIES, INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., SANDOZ, INC., MOMENTA PHARMACEUTICALS, INC., SYNTHON PHARMACEUTICALS INC., SYNTHON B.V., SYNTHON S.R.O., AND AMNEAL PHARMACEUTICALS LLC	)	
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 Doctor Reddy's Laboratories, Ltd. ("DRL Ltd.") and Doctor Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL"); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan"); Sandoz, Inc. and Momenta Pharmaceuticals, Inc. (collectively "Sandoz"); Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon s.r.o. (collectively "Synthon"); and Amneal Pharmaceuticals LLC ("Amneal") (collectively "Defendants").

NATURE OF THE ACTION

1. This is an action brought by Teva for infringement of United States Patent No. 8,969,302 ("the '302 patent"). This action arises out of Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs") seeking approval from 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 '302 patent.

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 at P.O. Box 95, Rehovot, 76100, Israel.

DRL

6. Upon information and belief, Doctor Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

7. Upon information and belief, Doctor Reddy's Laboratories Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107

College Road East, Princeton, NJ 08540, and is a wholly-owned subsidiary of Doctor Reddy's Laboratories Ltd.

Mylan

8. 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.

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

10. 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.

Sandoz

11. Upon information and belief, Sandoz, Inc. is a corporation organized and existing under the laws of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

12. Upon information and belief, Momenta Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142.

Synthon

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

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

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

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

Amneal

17. Upon information and belief, Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 400 Crossing Blvd., Third Floor, Bridgewater, NJ 08807-2863.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

19. 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.

Personal Jurisdiction Over DRL

20. Upon information and belief, this Court has personal jurisdiction over DRL because DRL did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDAs that are the subject matter of this lawsuit. *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 14-cv-1172-GMS (D. Del.).

21. Upon information and belief, this Court has personal jurisdiction over DRL Inc.

22. DRL Inc. has admitted that it is subject to personal jurisdiction in this district. *See Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1506 (D. Del.).

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

24. Upon information and belief, Defendant DRL Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

25. Upon information and belief, DRL Inc. routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter alia, allopurinol, amlodipine besylate-atorvastatin, amoxicillin, amoxicillin-clavulanate potassium, and anastrozole.

26. Upon information and belief, DRL Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, allopurinol, amlodipine besylate-atorvastatin, amoxicillin, amoxicillin-clavulanate potassium, and anastrozole.

27. Upon information and belief, Defendant DRL Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including within the State of Delaware.

28. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

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

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

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

32. By letter dated August 1, 2014, DRL Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206767 seeking approval to market DRL's Glatiramer Acetate Product ("DRL's First Notice Letter").

33. Further, upon information and belief, DRL Inc., affiliates of DRL Inc. and/or subsidiaries of DRL Inc. are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

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

35. Upon information and belief, this Court has personal jurisdiction over DRL Ltd.

36. DRL Ltd. has admitted that it is subject to personal jurisdiction in this district. *See Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1506 (D. Del.).

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

38. Upon information and belief, Defendant DRL Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

39. Upon information and belief, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter alia, ciprofloxacin, allopurinol, amlodipine besylate, atorvastatin calcium, and citalopram.

40. Upon information and belief, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, ciprofloxacin, allopurinol, amlodipine besylate, atorvastatin calcium, and citalopram.

41. Upon information and belief, Defendant DRL Ltd. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of Delaware.

42. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

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

44. Upon information and belief, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

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

46. By letter dated August 1, 2014, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) sent DRL's First Notice Letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206767 seeking approval to market DRL's Glatiramer Acetate Product.

47. Further, upon information and belief, DRL Ltd., affiliates of DRL Ltd. and/or subsidiaries of DRL Ltd. are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

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

49. Upon information and belief, this Court also has personal jurisdiction over DRL because it previously has been sued in this district, did not challenge 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., Genzyme Corporation, et al. v. Dr. Reddy's Laboratories Ltd., et al.*, C.A. No. 13-1506 (D. Del.); *Teijin Ltd., et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1780 (D. Del.); *Pfizer, et al. v. Dr. Reddy's Laboratories Ltd., et al.*, C.A. No. 13-989 (D. Del.); *Fresenius Kabi USA LLC v. Dr. Reddy's Laboratories Ltd., et al.*, C.A. No. 13-925 (D. Del.); *Novartis Pharmaceuticals Corp., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 14-157 (D. Del.).

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

51. Upon information and belief, DRL Ltd. will manufacture DRL's proposed generic version of COPAXONE® 40 mg/mL product on behalf of DRL Inc. and DRL Inc. will act as the agent of DRL Ltd. for sale of that product in the United States, including Delaware.

Personal Jurisdiction Over Mylan

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

53. 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. 10-306 (D. Del.); *Mylan Pharmaceuticals Inc., et al. v. Kremers Urban Development Co.*, C.A. No. 02-1628 (D. Del.); *Mylan Pharmaceuticals Inc., et*

al. v. Galderma Laboratories Inc. et al., C.A. No. 10-892 (D. Del.); *DuPont Merck Pharmaceutical Co., et al. v. Bristol-Myers Squibb Co., et al.*, C.A. No. 95-290 (D. Del.).

54. 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.

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

56. 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.

57. 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.

58. 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 rendering it at home in Delaware.

59. Upon information and belief, Mylan Pharmaceuticals Inc. routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter alia, abacavir sulfate, acyclovir, alprazolam, amitriptyline hydrochloride-chlordiazepoxide, and amlodipine besylate.

60. Upon information and belief, Mylan Pharmaceuticals Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products

in the State of Delaware, including, inter alia, abacavir sulfate, acyclovir, alprazolam, amitriptyline hydrochloride-chlordiazepoxide, and amlodipine besylate.

61. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product, for sale and use throughout the United States, including the State of Delaware.

62. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

63. 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 product throughout the United States, including in Delaware.

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

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

66. By letter dated August 28, 2014, Mylan Pharmaceuticals Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206936 seeking approval to market Mylan's Glatiramer Acetate Product ("Mylan's First Notice Letter").

67. 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. 13-1332 (D. Del.); *UCB Inc., et al. v. Mylan Inc., et al.*, C.A. No. 13-1214 (D. Del.); *Forest Laboratories Inc., et al v. Mylan Inc., et al.*, C.A. No. 13-1605 (D. Del.).

68. 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.

69. 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, and significant contacts with the forum, all of which render Defendant Mylan Pharmaceuticals Inc. at home in the forum.

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

71. 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. 10-306 (D. Del.); *Mylan Pharmaceuticals Inc., et al. v. Kremers Urban Development Co.*, C.A. No. 02-1628 (D. Del.); *Mylan Pharmaceuticals Inc., et al. v. Galderma Laboratories Inc., et al.*, C.A. No. 10-892 (D. Del.); *DuPont Merck Pharmaceutical Co., et al. v. Bristol-Myers Squibb Co., et al.*, C.A. No. 95-290 (D. Del.).

72. 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.

73. 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 rendering it at home in Delaware.

74. Upon information and belief, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter alia, albuterol sulfate, alendronate sodium, alprazolam, amitriptyline hydrochloride-perphenazine, and amlodipine besylate.

75. Upon information and belief, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, albuterol sulfate, alendronate sodium, alprazolam, amitriptyline hydrochloride-perphenazine, and amlodipine besylate.

76. Upon information and belief, Defendant Mylan Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product, for sale and use throughout the United States, including the State of Delaware.

77. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

78. Upon information and belief, Defendant Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

79. Upon information and belief, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

80. Upon information and belief, as a result of Mylan Inc.'s (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of Delaware, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

81. By letter dated August 28, 2014, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) sent Mylan's First Notice Letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206936 seeking approval to market Mylan's Glatiramer Acetate Product.

82. 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. 13-1332 (D. Del.); *UCB Inc., et al. v. Mylan Inc., et al.*, C.A. No. 13-1214 (D. Del.); *Forest Laboratories Inc., et al v. Mylan Inc., et al.*, C.A. No. 13-1605 (D. Del.).

83. 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.

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

85. Upon information and belief, Mylan Pharmaceuticals Inc. will manufacture Mylan's proposed generic version of COPAXONE® 40 mg/mL product on behalf of Mylan Inc. and Mylan Pharmaceuticals Inc. will act as the agent of Mylan Inc. for sale of that product in the United States, including Delaware.

Personal Jurisdiction Over Sandoz

86. Upon information and belief, this Court has personal jurisdiction over Sandoz Inc. and Momenta Pharmaceuticals, Inc. because they did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDAs that are the subject matter of this lawsuit. *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, C.A. No. 14-1171-GMS (D. Del.).

87. Upon information and belief, this Court has personal jurisdiction over Defendant Sandoz, Inc.

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

89. Upon information and belief, Defendant Sandoz, Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

90. Upon information and belief, Sandoz, Inc. routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter alia, amoxicillin-clavulanate potassium, atorvastatin calcium, decitabine, ceftriaxone sodium, and clindamycin phosphate.

91. Upon information and belief, Sandoz, Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, amoxicillin-clavulanate potassium, atorvastatin calcium, decitabine, ceftriaxone sodium, and clindamycin phosphate.

92. Upon information and belief, Defendant Sandoz, Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of Delaware.

93. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

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

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

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

97. By letter dated August 27, 2014, Sandoz, Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206921 seeking approval to market Sandoz's Glatiramer Acetate Product ("Sandoz's First Notice Letter").

98. Further, upon information and belief, Sandoz, Inc., affiliates of Sandoz, Inc. and/or subsidiaries of Sandoz, Inc. are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

99. Upon information and belief, this Court also has personal jurisdiction over Sandoz, Inc. because it previously has been sued in this district, did not challenge 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. Genzyme Corporation, et al. v. Sandoz, Inc.*, C.A. No. 13-1507 (D. Del.); *UCB Inc., et al. v. Sandoz, Inc.*, C.A. No. 13-1216 (D. Del.)); *Merck Sharp & Dohme Corp. v. Sandoz.*, C.A. No. 14-916 (D. Del.).

100. Upon information and belief, this Court has personal jurisdiction over Defendant Sandoz, Inc. for the reasons stated herein, including, inter alia, Defendant Sandoz, Inc.'s

activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendant Sandoz, Inc. at home in the forum.

101. Upon information and belief, this Court has personal jurisdiction over Defendant Momenta Pharmaceuticals, Inc.

102. Upon information and belief, Defendant Momenta Pharmaceuticals, Inc. is a company incorporated in the State of Delaware.

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

104. Upon information and belief, Defendant Momenta Pharmaceuticals, Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

105. Upon information and belief, Momenta Pharmaceuticals, Inc., through its business partner, Sandoz, Inc., has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, enoxaparin sodium.

106. Upon information and belief, Defendant Momenta Pharmaceuticals, Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of Delaware.

107. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

108. Upon information and belief, Defendant Momenta Pharmaceuticals, Inc. (through its business partner Sandoz, Inc.) has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

109. Upon information and belief, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz, Inc.) will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

110. Upon information and belief, as a result of Momenta Pharmaceuticals, Inc.'s (through its business partner Sandoz, Inc.) marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of Delaware, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

111. By letter dated August 27, 2014, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz, Inc.) sent Sandoz's First Notice Letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206921 seeking approval to market Sandoz's Glatiramer Acetate Product.

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

113. Upon information and belief, following any FDA approval of Sandoz's ANDA, Defendants Sandoz, Inc. and Momenta Pharmaceuticals, Inc. will work in concert with one

another to make, use, offer to sell, and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

114. Upon information and belief, Momenta Pharmaceuticals, Inc. will manufacture Sandoz's proposed generic version of COPAXONE® 40 mg/mL product on behalf of Sandoz, Inc. and Sandoz, Inc. will act as the agent of Momenta Pharmaceuticals, Inc. for sale of that product in the United States, including Delaware.

Personal Jurisdiction Over Synthon

115. Upon information and belief, this Court has personal jurisdiction over Synthon because Synthon did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDAs that are the subject matter of this lawsuit. *Teva Pharms. USA, Inc., et al. v. Synthon Pharms., Inc., et al.*, C.A. No. 14-1419-GMS (D. Del.).

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

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

118. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

119. Upon information and belief, Synthon routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, inter

alia, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

120. Upon information and belief, Synthon has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

121. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of Delaware.

122. Teva sells COPAXONE® 40 mg/mL product in the State of Delaware.

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

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

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

126. By letter dated October 8, 2014, Synthon Pharmaceuticals, Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206873 seeking approval to market Synthon's Glatiramer Acetate Product ("Synthon's First Notice Letter").

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

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

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

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

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

132. Upon information and belief, Defendant Synthon B.V. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, rendering it at home in Delaware.

133. Upon information and belief, Defendant Synthon B.V. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including within the State of Delaware.

134. Defendant Synthon B.V. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

135. Upon information and belief, Synthon B.V. caused its agent Synthon Pharmaceuticals Inc. to send Synthon's First Notice Letter to Teva, a Delaware corporation.

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

137. Upon information and belief, as a result of Synthon's marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of

Delaware, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

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

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

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

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

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

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

144. Upon information and belief, Defendant Synthon s.r.o. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, rendering it at home in Delaware.

145. Upon information and belief, Defendant Synthon s.r.o. 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® 40 mg/mL product for sale and use throughout the United States, including within the State of Delaware.

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

147. Upon information and belief, Synthon s.r.o. caused its agent Synthon Pharmaceuticals Inc. to send Synthon's First Notice Letter to Teva, a Delaware corporation.

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

149. Upon information and belief, as a result of Synthon's marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of

Delaware, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of Delaware.

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

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

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

153. Upon information and belief, Synthon B.V. and Synthon s.r.o. will manufacture Synthon's proposed generic version of COPAXONE® 40 mg/mL product on behalf of Synthon Pharmaceuticals Inc. and Synthon Pharmaceuticals Inc. will act as the agent of Synthon B.V. and/or Synthon s.r.o. for sale of that product in the United States, including Delaware.

Personal Jurisdiction Over Amneal

154. Upon information and belief, this Court has personal jurisdiction over Amneal because it did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDAs that are the subject matter of this lawsuit. *Teva Pharms. USA, Inc., et al. v. Amneal Pharms. LLC*, C.A. No. 15-124-GMS (D. Del.).

155. Upon information and belief, this Court has personal jurisdiction over Amneal.

156. Upon information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware.

157. Upon information and belief, Amneal is registered to conduct business with the State of Delaware and maintains as a registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

158. Upon information and belief, Amneal is registered pursuant to 24 Del. C. § 2540 to distribute its generic pharmaceutical products in Delaware.

159. Upon information and belief, Amneal holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

160. Upon information and belief, Amneal markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

161. Upon information and belief, Amneal has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

162. Upon information and belief, Amneal 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® 40 mg/mL product, for sale and use throughout the United States, including within the State of Delaware.

163. Upon information and belief, Amneal has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

164. Amneal, after submitting its ANDA to the FDA, mailed a Paragraph IV Certification notice letter ("Amneal's First Notice Letter") to Teva Pharmaceuticals USA, a Delaware corporation.

165. Upon information and belief, this Court also has personal jurisdiction over Amneal because it has previously been sued in this district without challenging this Court's jurisdiction over it and has availed itself of this forum previously by asserting counterclaims for the purposes of litigating a patent dispute. *See, e.g., Endo Pharms. Inc. v. Amneal Pharms. LLC*, 14-1382-RGA; *Forest Labs., Inc. v. Amneal Pharms. LLC*, 14-508-LPS; *UCB, Inc. v. Amneal Pharms. LLC*, 13-1208-LPS.

166. Upon information and belief, Amneal's systematic and continuous business contacts within Delaware render it at home in Delaware.

167. Upon information and belief, Amneal consented to jurisdiction in Delaware by registering to conduct business with the State of Delaware and maintaining a registered agent in Delaware.

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

Venue

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

BACKGROUND

The ’302 Patent

170. The ’302 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on March 3, 2015.

171. Ety Klinger is the named inventor of the ’302 patent.

172. Yeda is the sole owner by assignment of all rights, title and interest in the ’302 patent.

173. Teva Ltd. is the exclusive licensee of the ’302 patent.

174. The ’302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

175. A true and correct copy of the ’302 patent is attached as Exhibit A.

Teva’s COPAXONE® 40 mg/mL Product

176. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market COPAXONE® 40 mg/ml product.

177. Teva USA is the holder of New Drug Application (“NDA”) number 20-622, approved by the United States Food and Drug Administration (“FDA”) for the use of glatiramer acetate 40mg/mL three times per week, marketed as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

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

The DRL ANDA and Related Ongoing Litigation

179. DRL 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® 40mg/mL product ("DRL's Glatiramer Acetate Product"), prior to the expiration of United States Patent No. 8,232,250 ("the '250 patent") and United States Patent No. 8,399,413 ("the '413 patent").

180. FDA assigned the ANDA for DRL's Glatiramer Acetate Product the number 206767.

181. DRL 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 DRL's Glatiramer Acetate Product ("DRL's Paragraph IV Certification").

182. DRL's First Notice Letter notified Teva that DRL had filed ANDA No. 206767 seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

183. Teva received DRL's First Notice Letter no earlier than August 6, 2014.

184. On September 10, 2014, Teva sued DRL in this Court for patent infringement related to ANDA No. 206767. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 14-1172-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of DRL's First Notice Letter, which effectively stayed the FDA from granting final approval to DRL's ANDA No. 206767 prior to the expiration of 30 months from the date DRL's First Notice Letter was received by Teva.

185. Upon information and belief, prior to obtaining FDA approval for ANDA No. 206767, DRL intends to file with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '302 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its DRL's Glatiramer Acetate Product.

186. Upon information and belief, both Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206767.

The Mylan ANDA and Related Ongoing Litigation

187. 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® 40 mg/mL product ("Mylan's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

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

189. 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 First Paragraph IV Certification").

190. Mylan's First Notice Letter notified Teva that Mylan had filed ANDA No. 206936 seeking approval to market Mylan's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

191. Teva received Mylan's First Notice Letter no earlier than August 28, 2014.

192. 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 '302 patent 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 Second Paragraph IV Certification"). By letter dated March 9, 2015, Mylan notified Teva that it had filed an amendment to ANDA No. 206936 with a Paragraph IV certification related thereto seeking approval to market Mylan's Glatiramer Acetate Product prior to the expiration of the '302 patent ("Mylan's Second Notice Letter").

193. On October 6, 2014, Teva sued Mylan in this Court for patent infringement related to ANDA No. 206936. *See Teva Pharms. USA, Inc., et al. v. Mylan Pharms Inc., et al.*, C.A. No. 14-1278-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Mylan's First Notice Letter, which effectively stayed the FDA from granting final approval to Mylan's ANDA No. 206936 prior to the expiration of 30 months from the date Mylan's First Notice Letter was received by Teva.

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

The Sandoz ANDA and Related Ongoing Litigation

195. Sandoz 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® 40 mg/mL product ("Sandoz's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

196. FDA assigned the ANDA for Sandoz's Glatiramer Acetate Product the number 206921.

197. Sandoz 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 Sandoz’s Glatiramer Acetate Product (“Sandoz’s Paragraph IV Certification”).

198. Sandoz’s First Notice Letter notified Teva that Sandoz had filed ANDA No. 206921 seeking approval to market Sandoz’s Glatiramer Acetate Product prior to the expiration of the ’250 and ’413 patents.

199. Teva received Sandoz’s First Notice Letter no earlier than August 28, 2014.

200. Sandoz 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 ’302 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Sandoz’s Glatiramer Acetate Product (“Sandoz’s Second Paragraph IV Certification”). By letter dated March 6, 2015, Mylan notified Teva that it had filed an amendment to ANDA No. 206921 with a Paragraph IV certification related thereto seeking approval to market Mylan’s Glatiramer Acetate Product prior to the expiration of the ’302 patent (“Sandoz’s Second Notice Letter”).

201. On September 10, 2014, Teva sued Sandoz in this Court for patent infringement related to ANDA No. 206921. *See Teva Pharms. USA, Inc., et al. v. Sandoz, Inc., et al.*, C.A. No. 14-1171-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Sandoz’s First Notice Letter, which effectively stayed the FDA from granting final approval to Sandoz’s ANDA No. 206921 prior to the expiration of 30 months from the date Sandoz’s First Notice Letter was received by Teva.

202. Upon information and belief, both Sandoz, Inc. and Momenta Pharmaceuticals, Inc. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206921.

The Synthon ANDA and Related Ongoing Litigation

203. Synthon filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® 40 mg/mL product ("Synthon's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

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

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

206. Synthon's First Notice Letter notified Teva that Synthon had filed ANDA No. 206873 seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

207. Teva received Synthon's First Notice Letter no earlier than October 9, 2014.

208. Synthon also filed with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '302 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Synthon's Glatiramer Acetate Product ("Synthon's Second Paragraph IV Certification"). By

letter dated March 27, 2015, Synthon notified Teva that it had filed an amendment to ANDA No. 206873 with a Paragraph IV certification related thereto seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '302 patent ("Synthon's Second Notice Letter").

209. On November 18, 2014, Teva sued Synthon in this Court for patent infringement related to ANDA No. 206873. *See Teva Pharms. USA, Inc., et al. v. Synthon Pharms. Inc., et al.*, C.A. No. 14-1419-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Synthon's First Notice Letter, which effectively stayed the FDA from granting final approval to Synthon's ANDA No. 206873 prior to the expiration of 30 months from the date Synthon's First Notice Letter was received by Teva.

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

The Amneal ANDA and Related Ongoing Litigation

211. Amneal 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® 40 mg/mL product ("Amneal's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

212. FDA assigned the ANDA for Amneal's Glatiramer Acetate Product the number 207553.

213. Amneal 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 Amneal's Glatiramer Acetate Product ("Amneal's First Paragraph IV Certification").

214. Amneal's First Notice Letter notified Teva that Amneal had filed ANDA No. 207553 seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

215. Teva received Amneal's First Notice Letter on or about January 26, 2015.

216. Amneal 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 '302 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Amneal's Glatiramer Acetate Product ("Amneal's Second Paragraph IV Certification"). By letter dated March 18, 2015, Amneal notified Teva that it had filed an amendment to ANDA No. 207553 with a Paragraph IV certification related thereto seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '302 patent ("Amneal's Second Notice Letter").

217. On February 3, 2015, Teva sued Amneal in this Court for patent infringement related to ANDA No. 207553. *See Teva Pharms. USA, Inc., et al. v. Amneal Pharms. LLC*, C.A. No. 15-124-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Amneal's First Notice Letter, which effectively stayed the FDA from granting final approval to Amneal's ANDA No. 207553 prior to the expiration of 30 months from the date Amneal's First Notice Letter was received by Teva.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY DRL

218. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

219. Before filing of this action Teva notified DRL of the issuance of the ’302 patent and that the ’302 patent is listed in the Orange Book with respect to Teva’s COPAXONE® 40 mg/mL product.

220. The use of DRL’s Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the ’302 patent.

221. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL’s Glatiramer Acetate Product would infringe one or more claims of the ’302 patent.

222. Under 35 U.S.C. § 271(e)(2)(A), DRL’s submission to FDA of the DRL ANDA to obtain approval for DRL’s Glatiramer Acetate Product before the expiration of the ’302 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of DRL’s Glatiramer Acetate Product would infringe one or more claims of the ’302 patent.

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

224. Upon information and belief, DRL plans and intends to, and will, infringe the ’302 patent immediately and imminently upon approval of DRL’s ANDA.

225. Upon information and belief, immediately and imminently upon approval of DRL’s ANDA, DRL’s Glatiramer Acetate Product will be administered according to its labeling

and prescribing information causing direct infringement of the claims of the ’302 patent under 35 U.S.C. § 271(a).

226. Upon information and belief, DRL, 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 ’302 patent.

227. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the ’302 patent when DRL’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

228. Upon information and belief, DRL knows that DRL’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’302 patent and that DRL’s Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, DRL, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the ’302 patent immediately and imminently upon approval of the DRL’s ANDA.

229. The foregoing actions by DRL constitute and/or would constitute infringement of the ’302 patent, active inducement of infringement of the ’302 patent and/or contribution to the infringement by others of the ’302 patent.

230. Upon information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the ’302 patent, actively inducing infringement of the ’302 patent and/or contributing to the infringement by others of the ’302 patent.

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

232. DRL'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. 8,969,302 BY DRL

233. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

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

235. Such conduct will lead to direct infringement of one or more claims on the '302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '302 patent under 35 U.S.C. § 271(c).

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

237. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and DRL as to liability for the infringement of the '302 patent. DRL's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

238. Upon information and belief, DRL will knowingly and willfully infringe the '302 patent.

239. Teva will be irreparably harmed if DRL is not enjoined from infringing the '302 patent.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY MYLAN

240. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

241. Before filing of this action Teva notified Mylan of the issuance of the '302 patent and that the '302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

242. The use of Mylan's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '302 patent.

243. 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 '302 patent.

244. Under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to FDA of the Mylan ANDA to obtain approval for Mylan's Glatiramer Acetate Product before the expiration of the '302 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 would infringe one or more claims of the '302 patent.

245. 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.

246. Upon information and belief, Mylan plans and intends to, and will, infringe the ’302 patent immediately and imminently upon approval of Mylan’s ANDA.

247. Upon information and belief, immediately and imminently upon approval of Mylan’s ANDA, Mylan’s Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the ’302 patent under 35 U.S.C. § 271(a).

248. 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 ’302 patent.

249. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the ’302 patent when Mylan’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

250. Upon information and belief, Mylan knows that Mylan’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’302 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 ’302 patent immediately and imminently upon approval of the Mylan’s ANDA.

251. The foregoing actions by Mylan constitute and/or would constitute infringement of the ’302 patent, active inducement of infringement of the ’302 patent and/or contribution to the infringement by others of the ’302 patent.

252. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the ’302 patent, actively inducing infringement of the ’302 patent and/or contributing to the infringement by others of the ’302 patent.

253. 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.

254. 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. 8,969,302 BY MYLAN

255. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

256. 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.

257. Such conduct will lead to direct infringement of one or more claims on the ’302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the ’302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the ’302 patent under 35 U.S.C. § 271(c).

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

259. 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 ’302

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

260. Upon information and belief, Mylan will knowingly and willfully infringe the '302 patent.

261. Teva will be irreparably harmed if Mylan is not enjoined from infringing the '302 patent.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY SANDOZ

262. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

263. Before filing of this action Teva notified Sandoz of the issuance of the '302 patent and that the '302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

264. The use of Sandoz's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '302 patent.

265. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

266. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of the Sandoz ANDA to obtain approval for Sandoz's Glatiramer Acetate Product before the expiration of the '302 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

267. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Glatiramer

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

268. Upon information and belief, Sandoz plans and intends to, and will, infringe the '302 patent immediately and imminently upon approval of Sandoz's ANDA.

269. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, Mylan's Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '302 patent under 35 U.S.C. § 271(a).

270. Upon information and belief, Sandoz, 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 '302 patent.

271. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '302 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

272. Upon information and belief, Sandoz knows that Sandoz's Glatiramer Acetate Product is especially made or adapted for use in infringing the '302 patent and that Sandoz's Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '302 patent immediately and imminently upon approval of the Sandoz's ANDA.

273. The foregoing actions by Sandoz constitute and/or would constitute infringement of the ’302 patent, active inducement of infringement of the ’302 patent and/or contribution to the infringement by others of the ’302 patent.

274. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the ’302 patent, actively inducing infringement of the ’302 patent and/or contributing to the infringement by others of the ’302 patent.

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

276. Sandoz’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 VI FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,969,302 BY SANDOZ

277. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

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

279. Such conduct will lead to direct infringement of one or more claims on the ’302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the ’302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the ’302 patent under 35 U.S.C. § 271(c).

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

281. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Sandoz as to liability for the infringement of the '302 patent. Sandoz's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

282. Upon information and belief, Sandoz will knowingly and willfully infringe the '302 patent.

283. Teva will be irreparably harmed if Sandoz is not enjoined from infringing the '302 patent.

COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY SYNTHON

284. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

285. Before filing of this action Teva notified Synthon of the issuance of the '302 patent and that the '302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

286. The use of Synthon's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '302 patent.

287. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Synthon's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

288. Under 35 U.S.C. § 271(e)(2)(A), Synthon's submission to FDA of the Synthon ANDA to obtain approval for Synthon's Glatiramer Acetate Product before the expiration of the '302 patent constitutes an act of infringement, and if approved, the commercial manufacture, use,

offer to sell, sale, or importation of Synthon's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

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

290. Upon information and belief, Synthon plans and intends to, and will, infringe the '302 patent immediately and imminently upon approval of Synthon's ANDA.

291. Upon information and belief, immediately and imminently upon approval of Synthon's ANDA, Synthon's Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '302 patent under 35 U.S.C. § 271(a).

292. Upon information and belief, Synthon, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '302 patent.

293. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the '302 patent when Synthon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

294. Upon information and belief, Synthon knows that Synthon's Glatiramer Acetate Product is especially made or adapted for use in infringing the '302 patent and that Synthon's

Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Synthon, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '302 patent immediately and imminently upon approval of the Synthon's ANDA.

295. The foregoing actions by Synthon constitute and/or would constitute infringement of the '302 patent, active inducement of infringement of the '302 patent and/or contribution to the infringement by others of the '302 patent.

296. Upon information and belief, Synthon acted without a reasonable basis for believing that it would not be liable for infringing the '302 patent, actively inducing infringement of the '302 patent and/or contributing to the infringement by others of the '302 patent.

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

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

COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,969,302 BY SYNTHON

299. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

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

301. Such conduct will lead to direct infringement of one or more claims on the ’302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the ’302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the ’302 patent under 35 U.S.C. § 271(c).

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

303. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Synthon as to liability for the infringement of the ’302 patent. Synthon’s actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Synthon’s threatened imminent actions.

304. Upon information and belief, Synthon will knowingly and willfully infringe the ’302 patent.

305. Teva will be irreparably harmed if Synthon is not enjoined from infringing the ’302 patent.

COUNT IX FOR INFRINGEMENT OF U.S. PATENT NO. 8,969,302 BY AMNEAL

306. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

307. Before filing of this action Teva notified Amneal of the issuance of the ’302 patent and that the ’302 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

308. The use of Amneal’s Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the ’302 patent.

309. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

310. Under 35 U.S.C. § 271(e)(2)(A), Amneal's submission to FDA of the Amneal ANDA to obtain approval for Amneal's Glatiramer Acetate Product before the expiration of the '302 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '302 patent.

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

312. Upon information and belief, Amneal plans and intends to, and will, infringe the '302 patent immediately and imminently upon approval of Amneal's ANDA.

313. Upon information and belief, immediately and imminently upon approval of Amneal's ANDA, Amneal's Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '302 patent under 35 U.S.C. § 271(a).

314. Upon information and belief, Amneal, 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 ’302 patent.

315. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of the ’302 patent when Amneal’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

316. Upon information and belief, Amneal knows that Amneal’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’302 patent and that Amneal’s Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Amneal, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the ’302 patent immediately and imminently upon approval of the Amneal’s ANDA.

317. The foregoing actions by Amneal constitute and/or would constitute infringement of the ’302 patent, active inducement of infringement of the ’302 patent and/or contribution to the infringement by others of the ’302 patent.

318. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the ’302 patent, actively inducing infringement of the ’302 patent and/or contributing to the infringement by others of the ’302 patent.

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

320. Amneal'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 X FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,969,302 BY AMNEAL

321. The allegations of the proceeding paragraphs 1-217 are realleged and incorporated herein by reference.

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

323. Such conduct will lead to direct infringement of one or more claims on the '302 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '302 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '302 patent under 35 U.S.C. § 271(c).

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

325. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Amneal as to liability for the infringement of the '302 patent. Amneal's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

326. Upon information and belief, Amneal will knowingly and willfully infringe the '302 patent.

327. Teva will be irreparably harmed if Amneal is not enjoined from infringing the '302 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

Against all Defendants

(a) a judgment that the ’302 patent is valid and enforceable;

(b) a judgment that the case against all Defendants is exceptional and awarding Teva its attorneys’ fees under 35 U.S.C. § 285;

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

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

Against DRL

(e) a judgment that DRL’s submission of ANDA No. 206767 was an act of infringement of one or more claims of the ’302 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of DRL’s Glatiramer Acetate Product prior to the expiration of the ’302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’302 patent;

(f) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the DRL ANDA No. 206767 or any product the use of which infringes the ’302 patent, shall be a date that is not earlier than the expiration of the ’302 patent;

(g) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining DRL and all persons acting in concert with DRL from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing DRL’s Glatiramer Acetate Product, or any product the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent until after the expiration of the ’302 patents;

(h) an Order pursuant to 35 U.S.C. § 283 permanently enjoining DRL and all persons acting in concert with DRL from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing DRL's Glatiramer Acetate Product, or any product or compound the use of which infringes the '302 patent, or inducing or contributing to the infringement of the '302 patent, until after the expiration of the '302 patent;

(i) an Order enjoining DRL and all persons acting in concert with DRL from seeking, obtaining, or maintaining approval of the DRL ANDA No. 206767 before the expiration of the '302 patent;

(j) an award of Teva's damages or other monetary relief to compensate Teva if DRL engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of DRL's Glatiramer Acetate Product, or any product or compound the use of which infringes the '302 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '302 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

Against Mylan

(k) a judgment that Mylan's submission of ANDA No. 206936 was an act of infringement of one or more claims of the '302 patent 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 '302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '302 patent;

(l) 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 '302 patent, shall be a date that is not earlier than the expiration of the '302 patent;

(m) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan and all persons acting in concert with Mylan 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 '302 patent, or inducing or contributing to the infringement of the '302 patent until after the expiration of the '302 patents;

(n) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Mylan and all persons acting in concert with Mylan 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 '302 patent, or inducing or contributing to the infringement of the '302 patent, until after the expiration of the '302 patent;

(o) an Order enjoining Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of the Mylan ANDA No. 206936 before the expiration of the '302 patent;

(p) an award of Teva's damages or other monetary relief to compensate Teva if Mylan 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 '302 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '302 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

Against Sandoz

(q) a judgment that Sandoz's submission of ANDA No. 206921 was an act of infringement of one or more claims of the '302 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sandoz's Glatiramer Acetate Product prior to the

expiration of the ’302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’302 patent;

(r) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sandoz ANDA No. 206921 or any product the use of which infringes the ’302 patent, shall be a date that is not earlier than the expiration of the ’302 patent;

(s) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz’s Glatiramer Acetate Product, or any product the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent until after the expiration of the ’302 patents;

(t) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent, until after the expiration of the ’302 patent;

(u) an Order enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of the Sandoz ANDA No. 206921 before the expiration of the ’302 patent;

(v) an award of Teva’s damages or other monetary relief to compensate Teva if Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sandoz’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’302 patent, or the inducement or

contribution of the foregoing, prior to the expiration of the ’302 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

Against Synthon

(w) a judgment that Synthon’s submission of ANDA No. 206873 was an act of infringement of one or more claims of the ’302 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Synthon’s Glatiramer Acetate Product prior to the expiration of the ’302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’302 patent;

(x) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Synthon ANDA No. 206873 or any product the use of which infringes the ’302 patent, shall be a date that is not earlier than the expiration of the ’302 patent;

(y) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Synthon and all persons acting in concert with Synthon from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Synthon’s Glatiramer Acetate Product, or any product the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent until after the expiration of the ’302 patents;

(z) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Synthon and all persons acting in concert with Synthon from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Synthon’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent, until after the expiration of the ’302 patent;

(aa) an Order enjoining Synthon and all persons acting in concert with Synthon from seeking, obtaining, or maintaining approval of the Synthon ANDA No. 206873 before the expiration of the ’302 patent;

(bb) an award of Teva’s damages or other monetary relief to compensate Teva if Synthon engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Synthon’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’302 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’302 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

Against Amneal

(cc) a judgment that Amneal’s submission of ANDA No. 207553 was an act of infringement of one or more claims of the ’302 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Amneal’s Glatiramer Acetate Product prior to the expiration of the ’302 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’302 patent;

(dd) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Amneal ANDA No. 207553 or any product the use of which infringes the ’302 patent, shall be a date that is not earlier than the expiration of the ’302 patent;

(ee) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Amneal and all persons acting in concert with Amneal from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Amneal Glatiramer Acetate Product, or any product the use of which infringes the ’302 patent, or inducing or contributing to the infringement of the ’302 patent until after the expiration of the ’302 patents;

(ff) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Amneal and all persons acting in concert with Amneal from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Amneal's Glatiramer Acetate Product, or any product or compound the use of which infringes the '302 patent, or inducing or contributing to the infringement of the '302 patent, until after the expiration of the '302 patent;

(gg) an Order enjoining Amneal and all persons acting in concert with Amneal from seeking, obtaining, or maintaining approval of the Amneal ANDA No. 207553 before the expiration of the '302 patent; and

(hh) an award of Teva's damages or other monetary relief to compensate Teva if Amneal engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Amneal's Glatiramer Acetate Product, or any product or compound the use of which infringes the '302 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '302 patent in accordance with 35 U.S.C. § 271(e)(4)(C).

Friday, April 10, 2015

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