IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO., LTD., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. _____ |
| DOCTOR REDDY'S LABORATORIES, LTD., DOCTOR REDDY'S LABORATORIES, INC., SANDOZ, INC., MOMENTA PHARMACEUTICALS, INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., SYNTHON PHARMACEUTICALS INC., SYNTHON B.V., SYNTHON S.R.O., PFIZER INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL GMBH, BIOCON LTD. and APOTEX CORP., | ) | |
| 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., Synthon s.r.o., and Pfizer Inc. (collectively "Synthon"); Amneal Pharmaceuticals LLC ("Amneal LLC"), Amneal Pharmaceuticals Company GmbH

("Amneal GmbH") (collectively "Amneal"); and Biocon Ltd. and Apotex Corp. ("Apotex") (collectively "Biocon") (collectively "Defendants").

## NATURE OF THE ACTION

1. This is an action brought by Teva for infringement of United States Patent No. 9,402,874 ("the '874 patent"). This action arises out of Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs") with a certification under 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV Certification"), 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'874 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 11100 Nall Ave, Overland Park, Kansas 66211.

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.

17. Upon information and belief, Defendant Pfizer Inc. is a corporation organized and existing under the laws of Delaware with its principle place of business at 235 East 42nd Street, New York, NY 10017.

**Amneal**

18. 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.

19. Upon information and belief, Amneal GmbH is a limited liability company organized and existing under the laws of Switzerland with a principal place of business at Turnstrasse 30, 6312 Steinhausen – Switzerland.

**Biocon**

20. Upon information and belief, Biocon Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, India 560100.

21. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware with its principal place of business at 2400 N. Commerce Parkway, Weston, FL, 33326, and is a subsidiary of Apotex Inc.

## JURISDICTION AND VENUE

**Subject Matter Jurisdiction**

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

23. 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**

24. 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 its ANDA that is the subject matter of this lawsuit. *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

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

26. 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.).

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

28. 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.

29. 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.

30. 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.

31. 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.

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

33. 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.

34. 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.

35. 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.

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

37. By letter dated October 6, 2016, DRL Inc. notified Teva that it had filed an amendment to ANDA No. 206767 with a Paragraph IV certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '874 patent ("DRL's Fourth Notice Letter").

38. 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.

39. 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.

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

41. 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.).

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

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

48. 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.

49. 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.

50. 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.

51. By letter dated August 1, 2014, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) notified Teva that it had filed ANDA No. 206767 with a Paragraph IV certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patent.

52. By letter dated October 6, 2016, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) notified Teva that it had filed an amendment to ANDA No. 206767 with a Paragraph IV certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '874 patent.

53. 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.

54. 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.

55. 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.).

56. 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.

57. 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**

58. Upon information and belief, this Court has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. Mylan challenged this Court's exercise of personal jurisdiction over

them for purposes of litigating allegations of patent infringement involving its ANDA that is the subject matter of this lawsuit, but lost that challenge. *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del). After losing their challenge to personal jurisdiction, in the pretrial filings for *In re Copaxone*, Mylan did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving its ANDA that is the subject matter of this lawsuit. *See* D.I. 259, Redacted Version of Pretrial Order, *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

59. 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.).

60. 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.

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

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

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

69. 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.

70. 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.

71. 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.

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

73. Upon information and belief, prior to obtaining FDA approval for ANDA No. 206936, Mylan 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 '874 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan's Glatiramer Acetate Product.

74. 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.).

75. 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.

76. 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.

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

78. 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.).

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.

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

85. 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.

86. 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.

87. 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.

88. By letter dated August 28, 2014, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) notified Teva Pharmaceuticals USA, Inc., a Delaware corporation, that it had filed ANDA No. 206936, with a Paragraph IV Certification, seeking approval to market Mylan's Glatiramer Acetate Product.

89. Upon information and belief, prior to obtaining FDA approval for ANDA No. 206936, Mylan Inc. (through its wholly-owned subsidiary Defendant Mylan Pharmaceuticals Inc.) 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 '874 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan's Glatiramer Acetate Product.

90. 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.).

91. 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.

92. 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.

93. 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**

94. 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 its ANDA that is the subject matter of this lawsuit. *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

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

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

97. 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.

98. 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.

99. 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.

100. 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.

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

102. 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.

103. 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.

104. 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.

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

106. By letter dated August 4, 2016, Sandoz Ltd. notified Teva that it had filed an amendment to ANDA No. 206921 with a Paragraph IV certification related thereto seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '874 patent ("Sandoz's Fourth Notice Letter").

107. 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.

108. 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.).

109. 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.

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

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

112. 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.

113. 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.

114. 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.

115. 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.

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

117. 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.

118. 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.

119. 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.

120. By letter dated August 27, 2014, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz, Inc.) notified Teva Pharmaceuticals USA, Inc., a Delaware corporation,

that it had filed ANDA No. 206921, with a Paragraph IV Certification, seeking approval to market Sandoz's Glatiramer Acetate Product.

121. By letter dated August 4, 2016, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz, Inc.) notified Teva that it had filed an amendment to ANDA No. 206921 with a Paragraph IV certification related thereto seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '874 patent.

122. 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.

123. 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.

124. 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**

125. 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 its ANDA that is the subject matter of this lawsuit. *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

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

127. 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.

128. 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.

129. 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.

130. 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.

131. 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.

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

133. 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.

134. 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.

135. 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.

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

137. By letter dated August 31, 2016, Synthon Pharmaceuticals, Inc. 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 '874 patent ("Synthon's Fourth Notice Letter").

138. 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.

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

140. 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.

141. 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.

142. 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.

143. 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.

144. 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.

145. 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.

146. 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.

147. 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.

148. 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.

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

150. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon B.V. for the reasons stated herein, including, *inter alia*, 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.

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

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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.

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

159. 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.

160. 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.

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

162. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon s.r.o. for the reasons stated herein, including, *inter alia*, 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.

163. 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.

164. 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.

165. Upon information and belief, this Court has personal jurisdiction over Defendant Pfizer Inc.

166. Upon information and belief, Defendant Pfizer Inc. is incorporated in Delaware.

167. Upon information and belief, Defendant Pfizer Inc. markets, distributes and/or sells pharmaceutical drug products within the State of Delaware and throughout the United States.

168. Upon information and belief, Defendant Pfizer 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.

169. Upon information and belief, Defendant Pfizer 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.

170. Upon information and belief, Defendant Pfizer Inc. has entered into an agreement with Synthon B.V. to commercialize a generic version of COPAXONE® 40 mg/mL product

throughout the United States, including in Delaware. *See* http://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_synthon_enter_into_u_s_commercialization_agreement_for_potential_generic_treatment_of_multiple_sclerosis.

171. Upon information and belief, Pfizer Inc. will market, sell, and offer for sale, in collaboration with Synthon B.V., a proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

172. Upon information and belief, this Court has personal jurisdiction over Defendant Pfizer Inc. because Pfizer Inc. is incorporated in Delaware.

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

**Personal Jurisdiction Over Amneal**

174. Upon information and belief, this Court has personal jurisdiction over Amneal LLC 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. *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

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

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

177. Upon information and belief, Amneal LLC 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.

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

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

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

181. Upon information and belief, Amneal LLC 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.

182. Upon information and belief, Amneal LLC 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.

183. Upon information and belief, Amneal LLC collaborated and/or acted in concert with Amneal GmbH 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.

184. By letter dated January 23, 2015, Amneal LLC notified Teva Pharmaceuticals USA, Inc., a Delaware corporation, that it had filed ANDA No. 207553, which included a Paragraph IV Certification, seeking approval to market Amneal's Glatiramer Acetate Product ("Amneal's First Notice Letter").

185. By letter dated August 24, 2016, Amneal LLC 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 '874 patent ("Amneal's Fourth Notice Letter").

186. Upon information and belief, this Court also has personal jurisdiction over Amneal LLC 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.

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

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

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

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

191. Upon information and belief, Amneal GmbH 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.

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

193. Upon information and belief, Amneal GmbH, directly or indirectly through its agent Amneal LLC, markets, distributes, and/or sells generic drugs throughout the United States and within the State of Delaware.

194. By letter dated August 24, 2016, Amneal GmbH (through its agent Amneal LLC) 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 '874 patent.

195. Upon information and belief, this Court also has personal jurisdiction over Amneal GmbH under Federal Rule of Civil Procedure 4(k)(2).

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

**Personal Jurisdiction Over Biocon**

197. Upon information and belief, this Court has personal jurisdiction over Biocon Ltd. because Biocon did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving its ANDA that is the subject matter of this lawsuit. *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. and Apotex Corp.*, C.A. No. 16-278-GMS (D. Del.).

198. Upon information and belief, this Court has personal jurisdiction over Biocon Ltd.

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

200. Upon information and belief, Biocon Ltd. has filed ANDAs in the United States and markets at least one generic pharmaceutical product in the State of Delaware, simvastatin.

201. Upon information and belief, Biocon Ltd. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including simvastatin.

202. Upon information and belief, Biocon Ltd., in conjunction with Apotex 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.

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

204. Upon information and belief, Biocon Ltd., in conjunction with its authorized U.S. agent Apotex, 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.

205. Upon information and belief, Biocon Ltd., in conjunction with Apotex, will market, sell, and offer for sale Defendants' proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

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

207. By letter dated March 10, 2016, Biocon Ltd. notified Teva Pharmaceuticals USA, Inc., a Delaware corporation, that it had filed ANDA No. 209001, which included a Paragraph IV Certification, seeking approval to market Biocon's Glatiramer Acetate Product ("Biocon's First Notice Letter").

208. By letter dated November 22, 2016, Biocon Ltd. notified Teva that it had filed an amendment to ANDA No. 209001 with a Paragraph IV certification related thereto seeking approval to market Biocon's Glatiramer Acetate Product prior to the expiration of the '874 patent ("Biocon's Second Notice Letter").

209. In the alternative, this Court has personal jurisdiction over Biocon Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Biocon Ltd.'s submission of an ANDA filing. Biocon Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction. Exercising jurisdiction over Biocon Ltd. is consistent with the Constitution and laws of the United States.

210. Upon information and belief, Biocon Pharma Inc. is a step-down subsidiary of Biocon Ltd. and is a corporation organized and existing under the laws of Delaware with its principal place of business at 484 U.S. 1 S., Ste B305, Iselin, NJ 08830.

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

**Personal Jurisdiction Over Apotex**

212. Upon information and belief, this Court has personal jurisdiction over Apotex because Apotex did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving its ANDA that is the subject matter of this lawsuit. *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. and Apotex Corp.*, C.A. No. 16-278-GMS (D. Del.).

213. Upon information and belief, this Court has personal jurisdiction over Apotex.

214. Upon information and belief, Apotex is incorporated in the State of Delaware, rendering it at home in Delaware.

215. Upon information and belief, Apotex 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. Apotex has availed itself of this Court by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court's jurisdiction in numerous legal proceedings. *See, e.g.*, *Sanofi-Aventis et al. v. Apotex Inc. et al.*, C.A. No. 07-792-GMS (D. Del.); *Warner Chilcott Co., LLC et al. v. Apotex Inc. et al.*, C.A. No. 14-998-GMS (D. Del.); *R-Tech Ueno, Ltd. v. Apotex Inc.*, C.A. No. 15-592-SLR (D.

Del.); *OSI Pharmaceuticals, LLC et al. v. Apotex Inc. et al.*, C.A. No. 15-772-SLR (D. Del.); *Salix Pharmaceuticals, Inc. et al. v. Apotex, Inc. et al*., C.A. No. 15-880-GMS (D. Del.); *Vanda Pharmaceuticals Inc. v. Apotex Inc.*, C.A. No. 15-922-GMS (D. Del.); *Shire Development LLC et al. v. Apotex Inc.*, C.A. No. 15-1045-LPS (D. Del.).

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

217. Upon information and belief, Apotex 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.

218. Upon information and belief, Apotex routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, amiodarone hydrochloride, azithromycin, cabergoline, clarithromycin, hydrochlorothiazide/losartan potassium, hydrochlorothiazide/quinapril hydrochloride, losartan potassium, montelukast sodium, mycophenolate mofetil, naratriptan hydrochloride, riluzole, sildenafil citrate, tolterodine tartrate, verapamil hydrochloride, and ziprasidone hydrochloride.

219. Upon information and belief, Apotex has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, amiodarone hydrochloride, azithromycin, cabergoline, clarithromycin, hydrochlorothiazide/losartan potassium, hydrochlorothiazide/quinapril hydrochloride, losartan potassium, montelukast sodium, mycophenolate mofetil, naratriptan hydrochloride, riluzole, sildenafil citrate, tolterodine tartrate, verapamil hydrochloride, and ziprasidone hydrochloride.

220. Upon information and belief, Apotex, in conjunction with Biocon 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 within the State of Delaware.

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

222. Upon information and belief, Apotex has partnered with Biocon Ltd. to seek FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in Delaware.

223. Upon information and belief, Apotex, in conjunction with Biocon Ltd., will market, sell, and offer for sale Defendants' proposed generic version of COPAXONE® 40 mg/mL product in the State of Delaware following FDA approval of that product.

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

225. Apotex is identified as Biocon's authorized U.S. agent in Biocon's First and Second Notice Letters.

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

**Venue**

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

**BACKGROUND**

**The '874 Patent**

228. The '874 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was duly and legally issued on August 2, 2016.

229. Ety Klinger is the named inventor of the '874 patent.

230. Yeda is the sole owner by assignment of all rights, title and interest in the '874 patent.

231. Yeda has granted Teva Ltd. an exclusive license in, to and under the '874 patent.

232. Teva Ltd. has granted Teva USA an exclusive license under the '874 patent to use, offer to sell, sell and import the COPAXONE 40 mg/mL product in the United States.

233. The '874 patent is listed in the Orange Book with respect to COPAXONE® 40 mg/mL product.

234. A true and correct copy of the '874 patent is attached as Exhibit A.

**Teva's COPAXONE® 40 mg/mL Product**

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

236. 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 40 mg/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.

237. 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**

238. 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").

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

240. 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").

241. DRL's First Notice Letter notified Teva that DRL had filed ANDA No. 206767, with a Paragraph IV Certification, seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

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

243. On September 10, 2014, Teva sued DRL in this Court for patent infringement related to ANDA No. 206767 and the '250 and '413 patents. *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.

244. 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 U.S. Patent No. 8,969,302 ("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 ("DRL's Second Paragraph IV Certification").

245. By letter dated May 19, 2015, DRL notified Teva that it had filed an amendment to ANDA No. 206767 with a Paragraph IV Certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '302 patent ("DRL's Second Notice Letter").

246. Teva received DRL's Second Notice Letter no earlier than May 19, 2015.

247. On April 10, 2015, Teva sued DRL in this Court for patent infringement related to ANDA No. 206767 and the '302 patent. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 15-0306-GMS (D. Del.).

248. On March 9, 2015, this Court ordered the consolidation of Civil Action No. 14-1172-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 14-1172-GMS (D. Del).

249. On May 15, 2015, this Court ordered the consolidation of Civil Action No. 15-0306-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-0306-GMS (D. Del).

250. On November 10, 2015, Teva sued DRL in this Court for patent infringement related to ANDA No. 206767 and U.S. Patent No. 9,155,776 ("the '776 patent"). *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

251. 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 '776 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 ("DRL's Third Paragraph IV Certification").

252. By letter dated January 14, 2016, DRL notified Teva that it had filed an amendment to ANDA No. 206767 with DRL's Third Paragraph IV Certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '776 patent ("DRL's Third Notice Letter").

253. Teva received DRL's Third Notice Letter no earlier than January 14, 2016.

254. 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 '874 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 ("DRL's Fourth Paragraph IV Certification").

255. By letter dated October 6, 2016, DRL notified Teva that it had filed an amendment to ANDA No. 206767 with DRL's Fourth Paragraph IV Certification related thereto seeking approval to market DRL's Glatiramer Acetate Product prior to the expiration of the '874 patent.

256. Teva received DRL's Fourth Notice Letter no earlier than October 6, 2016.

**The Mylan ANDA and Related Ongoing Litigation**

257. 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.

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

259. 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").

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

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

262. On October 6, 2014, Teva sued Mylan in this Court for patent infringement related to ANDA No. 206936 and the '250 and '413 patents. *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.

263. 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").

264. 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").

265. Teva received Mylan's Second Notice Letter no earlier than March 9, 2015.

266. On April 10, 2015, Teva sued Mylan in this Court for patent infringement related to ANDA No. 206936 and the '302 patent. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 15-0306-GMS (D. Del.).

267. On March 9, 2015, this Court ordered the consolidation of Civil Action No. 14-1278-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 14-1278-GMS (D. Del).

268. On May 15, 2015, this Court ordered the consolidation of Civil Action No. 15-0306-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-0306-GMS (D. Del).

269. On November 10, 2015, Teva sued Mylan in this Court for patent infringement related to ANDA No. 206936 and the '776 patent. *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

270. 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 '776 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 Third Paragraph IV Certification").

271. By letter dated February 17, 2016, Mylan notified Teva that it had filed an amendment to ANDA No. 206936 with Mylan's Third Paragraph IV Certification related thereto seeking approval to market Mylan's Glatiramer Acetate Product prior to the expiration of the '776 patent ("Mylan's Third Notice Letter").

272. Teva received Mylan's Third Notice Letter no earlier than February 17, 2016.

273. Upon information and belief, prior to obtaining FDA approval for ANDA No. 206936, Mylan 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 '874 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan's Glatiramer Acetate Product.

274. 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**

275. 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.

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

277. 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 First Paragraph IV Certification").

278. Sandoz's First Notice Letter notified Teva that Sandoz had filed ANDA No. 206921, with Sandoz's First Paragraph IV Certification, seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

279. Teva received Sandoz's First Notice Letter no earlier than August 28, 2014.

280. On September 10, 2014, Teva sued Sandoz in this Court for patent infringement related to ANDA No. 206921 and the '250 and '413 patents. *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.

281. 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").

282. By letter dated March 6, 2015, Sandoz notified Teva that it had filed an amendment to ANDA No. 206921 with Sandoz's Second Paragraph IV Certification related thereto seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '302 patent ("Sandoz's Second Notice Letter").

283. Teva received Sandoz's Second Notice Letter no earlier than March 6, 2015.

284. On April 10, 2015, Teva sued Sandoz in this Court for patent infringement related to ANDA No. 206921 and the '302 patent. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 15-0306-GMS (D. Del.).

285. On May 15, 2015, this Court ordered the consolidation of Civil Action No. 15-0306-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-0306-GMS (D. Del).

286. On November 10, 2015, Teva sued Sandoz in this Court for patent infringement related to ANDA No. 206921 and the '776 patent. *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

287. 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 '776 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 Third Paragraph IV Certification").

288. By letter dated January 22, 2016, Sandoz notified Teva that it had filed an amendment to ANDA No. 206921 with Sandoz's Third Paragraph IV Certification related thereto seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '776 patent ("Sandoz's Third Notice Letter").

289. Teva received Sandoz's Third Notice Letter no earlier than January 22, 2016.

290. 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 '874 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 Fourth Paragraph IV Certification").

291. By letter dated August 4, 2016, Sandoz notified Teva that it had filed an amendment to ANDA No. 206921 with Sandoz's Fourth Paragraph IV Certification related thereto seeking approval to market Sandoz's Glatiramer Acetate Product prior to the expiration of the '874 patent.

292. Teva received Sandoz's Fourth Notice Letter no earlier than August 4, 2016.

293. 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**

294. 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.

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

296. 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").

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

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

299. On November 18, 2014, Teva sued Synthon in this Court for patent infringement related to ANDA No. 206873 and the '250 and '413 patents. *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.

300. 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").

301. By letter dated March 27, 2015, Synthon notified Teva that it had filed an amendment to ANDA No. 206873 with Synthon's Second 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").

302. Teva received Synthon's Second Notice Letter no earlier than March 27, 2015.

303. On April 10, 2015, Teva sued Synthon in this Court for patent infringement related to ANDA No. 206873 and the '302 patent. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 15-0306-GMS (D. Del.).

304. On March 9, 2015, this Court ordered the consolidation of Civil Action No. 14-1419-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 14-1419-GMS (D. Del).

305. On May 15, 2015, this Court ordered the consolidation of Civil Action No. 15-0306-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-0306-GMS (D. Del).

306. On October 9, 2015, Synthon filed an unopposed motion to add Pfizer Inc. to the case. *See* D.I. 105, *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

307. On November 10, 2015, Teva sued Synthon in this Court for patent infringement related to ANDA No. 206873 and the '776 patent. *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

308. 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 '776 and '874 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 Third Paragraph IV Certification").

309. By letter dated August 31, 2016, Synthon notified Teva that it had filed an amendment to ANDA No. 206873 with Synthon's Third Paragraph IV certification related thereto seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '776 and '874 patents ("Synthon's Third Notice Letter").

310. Teva received Synthon's Third Notice Letter no earlier than August 31, 2016.

311. 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**

312. Amneal GmbH, through its U.S. agent Amneal LLC, 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.

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

314. Amneal GmbH 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").

315. Amneal LLC's First Notice Letter notified Teva that Amneal LLC had filed ANDA No. 207553, with Amneal's First Paragraph IV Certification seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents.

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

317. Amneal LLC's First Notice Letter did not identify that Amneal GmbH was the applicant of ANDA No. 207553.

318. On February 3, 2015, Teva sued Amneal LLC in this Court for patent infringement related to ANDA No. 207553 and the '250 and '413 patents. *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 LLC'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 LLC's First Notice Letter was received by Teva.

319. 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 Amneal's Glatiramer Acetate Product ("Amneal's Second Paragraph IV Certification").

320. By letter dated March 18, 2015, Amneal LLC 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 LLC's Second Notice Letter").

321. Amneal LLC's Second Notice Letter did not identify that Amneal GmbH was the applicant of ANDA No. 207553.

322. Teva received Amneal LLC's Second Notice Letter on or about March 18, 2015.

323. On April 10, 2015, Teva sued Amneal in this Court for patent infringement related to ANDA No. 207553 and the '302 patent. *See Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs., Ltd., et al.*, C.A. No. 15-0306-GMS (D. Del.).

324. On May 7, 2015, Teva filed a First Amended Complaint in *Teva Pharms. USA, Inc., et al. v. Amneal Pharms. LLC*, C.A. No. 15-306-GMS (D. Del.). The First Amended Complaint named both Amneal LLC and Amneal GmbH as defendants.

325. On March 9, 2015, this Court ordered the consolidation of Civil Action No. 15-124-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-0124-GMS (D. Del).

326. On May 15, 2015, this Court ordered the consolidation of Civil Action No. 15-306-GMS for all purposes, including trial, with the actions consolidated under Civil Action 14-1171-GMS. *See In re Copaxone*, C.A. No. 15-306-GMS (D. Del).

327. 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 '776 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Amneal's Glatiramer Acetate Product ("Amneal's Third Paragraph IV Certification").

328. By letter dated October 29, 2015, Amneal LLC notified Teva that it had filed an amendment to ANDA No. 207553 with Amneal's Third Paragraph IV certification related thereto seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '776 patent ("Amneal LLC's Third Notice Letter").

329. Teva received Amneal LLC's Third Notice Letter no earlier than October 29, 2015.

330. On November 10, 2015, Teva sued Amneal in this Court for patent infringement related to ANDA No. 207553 and the'776 patent. *See In re Copaxone*, C.A. No. 14-1171-GMS (D. Del).

331. 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 '874 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Amneal's Glatiramer Acetate Product ("Amneal's Fourth Paragraph IV Certification").

332. By letter dated August 24, 2016, Amneal LLC notified Teva that it had filed an amendment to ANDA No. 207553 with Amneal's Fourth Paragraph IV certification related

thereto seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '874 patent.

333. Teva received Amneal LLC's Fourth Notice Letter no earlier than August 24, 2016.

334. Upon information and belief, Amneal LLC and Amneal GmbH submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 207553.

**The Biocon ANDA and Related Ongoing Litigation**

335. Biocon Ltd., through its U.S. agent Apotex, 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 ("Biocon's Glatiramer Acetate Product"), prior to the expiration of the '250, '413, '302, and '776 patents.

336. FDA assigned the ANDA for Biocon's Glatiramer Acetate Product the number 209001.

337. Biocon Ltd. 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, '413, '302, and '776 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Biocon's Glatiramer Acetate Product ("Biocon's First Paragraph IV Certification").

338. Biocon Ltd.'s First Notice Letter notified Teva that Biocon Ltd. had filed ANDA No. 209001, with Biocon's First Paragraph IV Certification, seeking approval to market Biocon's Glatiramer Acetate Product prior to the expiration of the '250, '413, '302, and '776 patents.

339. Teva received Biocon Ltd.'s First Notice Letter on or about March 10, 2016.

340. On April 19, 2016, Teva sued Biocon Ltd. in this Court for patent infringement related to ANDA No. 209001 and the '250, '413, '302, and '776 patents. *See Teva Pharms. USA, Inc., et al. v. Biocon Ltd. and Apotex Corp.*, C.A. No. 16-278-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Biocon Ltd.'s First Notice Letter, which effectively stayed the FDA from granting final approval to Biocon's ANDA No. 209001 prior to the expiration of 30 months from the date Biocon Ltd.'s First Notice Letter was received by Teva.

341. Biocon Ltd. 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 '874 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Biocon's Glatiramer Acetate Product ("Biocon's Second Paragraph IV Certification").

342. By letter dated November 22, 2016, Biocon Ltd. notified Teva that it had filed an amendment to ANDA No. 209001 with Biocon's Second Paragraph IV certification related thereto seeking approval to market Biocon's Glatiramer Acetate Product prior to the expiration of the '874 patent.

343. Teva received Biocon's Second Notice Letter no earlier than November 22, 2016.

344. Upon information and belief, Biocon Ltd. and Apotex submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 209001.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY DRL**

345. The allegations of the proceeding paragraphs 1-344 are realleged and incorporated herein by reference.

346. Before filing of this action, the '874 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

347. The use of DRL's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '874 patent.

348. 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 '874 patent.

349. Under 35 U.S.C. § 271(e)(2)(A), DRL's submission to the FDA of the DRL ANDA with a Paragraph IV Certification to obtain approval for DRL's Glatiramer Acetate Product before the expiration of the '874 patent constitutes, or will constitute, 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 '874 patent.

350. 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.

351. Upon information and belief, DRL plans and intends to, and will, infringe the '874 patent immediately and imminently upon approval of DRL's ANDA.

352. 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 '874 patent under 35 U.S.C. § 271(a).

353. 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 ’874 patent.

354. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the ’874 patent when DRL’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

355. Upon information and belief, DRL knows that DRL’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’874 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 ’874 patent immediately and imminently upon approval of the DRL’s ANDA.

356. The foregoing actions by DRL constitute and/or would constitute infringement of the ’874 patent, active inducement of infringement of the ’874 patent and/or contribution to the infringement by others of the ’874 patent.

357. Upon information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the ’874 patent, actively inducing infringement of the ’874 patent and/or contributing to the infringement by others of the ’874 patent.

358. 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. 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. 9,402,874 BY DRL**

359. The allegations of the proceeding paragraphs 1-358 are realleged and incorporated herein by reference.

360. 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.

361. Such conduct will lead to direct infringement of one or more claims on the '874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '874 patent under 35 U.S.C. § 271(c).

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

363. 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 '874 patent. DRL's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

364. Upon information and belief, DRL will knowingly and willfully infringe the '874 patent.

365. Teva will be irreparably harmed if DRL is not enjoined from infringing the '874 patent.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY MYLAN**

366. The allegations of the proceeding paragraphs 1-365 are realleged and incorporated herein by reference.

367. Before filing of this action, the ’874 patent was listed in the Orange Book with respect to Teva’s COPAXONE® 40 mg/mL product.

368. The use of Mylan’s Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the ’874 patent.

369. 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 ’874 patent.

370. Under 35 U.S.C. § 271(e)(2)(A), Mylan’s submission to the FDA of the Mylan ANDA with a Paragraph IV Certification to obtain approval for Mylan’s Glatiramer Acetate Product before the expiration of the ’874 patent constitutes, or will constitute, 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 ’874 patent.

371. 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.

372. Upon information and belief, Mylan plans and intends to, and will, infringe the ’874 patent immediately and imminently upon approval of Mylan’s ANDA.

373. 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 '874 patent under 35 U.S.C. § 271(a).

374. 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 '874 patent.

375. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '874 patent when Mylan's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

376. Upon information and belief, Mylan knows that Mylan's Glatiramer Acetate Product is especially made or adapted for use in infringing the '874 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 '874 patent immediately and imminently upon approval of the Mylan's ANDA.

377. The foregoing actions by Mylan constitute and/or would constitute infringement of the '874 patent, active inducement of infringement of the '874 patent and/or contribution to the infringement by others of the '874 patent.

378. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '874 patent, actively inducing infringement of the '874 patent and/or contributing to the infringement by others of the '874 patent.

379. 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.

380. 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. 9,402,874 BY MYLAN**

381. The allegations of the proceeding paragraphs 1-380 are realleged and incorporated herein by reference.

382. 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.

383. Such conduct will lead to direct infringement of one or more claims on the '874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '874 patent under 35 U.S.C. § 271(c).

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

385. 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 '874 patent. Mylan's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Mylan's threatened imminent actions.

386. Upon information and belief, Mylan will knowingly and willfully infringe the '874 patent.

387. Teva will be irreparably harmed if Mylan is not enjoined from infringing the '874 patent.

**COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY SANDOZ**

388. The allegations of the proceeding paragraphs 1-387 are realleged and incorporated herein by reference.

389. Before filing of this action, the '874 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

390. The use of Sandoz's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '874 patent.

391. 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 '874 patent.

392. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to the FDA of the Sandoz ANDA with a Paragraph IV Certification to obtain approval for Sandoz's Glatiramer Acetate Product before the expiration of the '874 patent constitutes, or will constitute, 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 '874 patent.

393. 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.

394. Upon information and belief, Sandoz plans and intends to, and will, infringe the '874 patent immediately and imminently upon approval of Sandoz's ANDA.

395. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, Sandoz's Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '874 patent under 35 U.S.C. § 271(a).

396. 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 '874 patent.

397. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '874 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

398. Upon information and belief, Sandoz knows that Sandoz's Glatiramer Acetate Product is especially made or adapted for use in infringing the '874 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 '874 patent immediately and imminently upon approval of the Sandoz's ANDA.

399. The foregoing actions by Sandoz constitute and/or would constitute infringement of the ’874 patent, active inducement of infringement of the ’874 patent and/or contribution to the infringement by others of the ’874 patent.

400. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the ’874 patent, actively inducing infringement of the ’874 patent and/or contributing to the infringement by others of the ’874 patent.

401. 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.

402. 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. 9,402,874 BY SANDOZ**

403. The allegations of the proceeding paragraphs 1-402 are realleged and incorporated herein by reference.

404. 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.

405. Such conduct will lead to direct infringement of one or more claims on the ’874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the ’874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the ’874 patent under 35 U.S.C. § 271(c).

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

407. 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 '874 patent. Sandoz's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

408. Upon information and belief, Sandoz will knowingly and willfully infringe the '874 patent.

409. Teva will be irreparably harmed if Sandoz is not enjoined from infringing the '874 patent.

**COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY SYNTHON**

410. The allegations of the proceeding paragraphs 1-409 are realleged and incorporated herein by reference.

411. Before filing of this action, the '874 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

412. The use of Synthon's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '874 patent.

413. 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 '874 patent.

414. Under 35 U.S.C. § 271(e)(2)(A), Synthon's submission to the FDA of the Synthon ANDA with a Paragraph IV Certification to obtain approval for Synthon's Glatiramer Acetate Product before the expiration of the '874 patent constitutes, or will constitute, 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 '874 patent.

415. 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.

416. Upon information and belief, Synthon plans and intends to, and will, infringe the '874 patent immediately and imminently upon approval of Synthon's ANDA.

417. 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 '874 patent under 35 U.S.C. § 271(a).

418. 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 '874 patent.

419. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the '874 patent when Synthon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

420. Upon information and belief, Synthon knows that Synthon's Glatiramer Acetate Product is especially made or adapted for use in infringing the '874 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 '874 patent immediately and imminently upon approval of the Synthon's ANDA.

421. The foregoing actions by Synthon constitute and/or would constitute infringement of the '874 patent, active inducement of infringement of the '874 patent and/or contribution to the infringement by others of the '874 patent.

422. Upon information and belief, Synthon acted without a reasonable basis for believing that it would not be liable for infringing the '874 patent, actively inducing infringement of the '874 patent and/or contributing to the infringement by others of the '874 patent.

423. 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.

424. 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. 9,402,874 BY SYNTHON**

425. The allegations of the proceeding paragraphs 1-424 are realleged and incorporated herein by reference.

426. 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.

427. Such conduct will lead to direct infringement of one or more claims on the '874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '874 patent under 35 U.S.C. § 271(c).

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

429. 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 '874 patent. Synthon's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Synthon's threatened imminent actions.

430. Upon information and belief, Synthon will knowingly and willfully infringe the '874 patent.

431. Teva will be irreparably harmed if Synthon is not enjoined from infringing the '874 patent.

**COUNT IX FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY AMNEAL**

432. The allegations of the proceeding paragraphs 1-431 are realleged and incorporated herein by reference.

433. Before filing of this action, the '874 patent was listed in the Orange Book with respect to Teva's COPAXONE® 40 mg/mL product.

434. The use of Amneal's Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the '874 patent.

435. 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 '874 patent.

436. Under 35 U.S.C. § 271(e)(2)(A), Amneal's submission to the FDA of the Amneal ANDA with a Paragraph IV Certification to obtain approval for Amneal's Glatiramer Acetate Product before the expiration of the '874 patent constitutes, or will constitute. 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 '874 patent.

437. 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.

438. Upon information and belief, Amneal plans and intends to, and will, infringe the '874 patent immediately and imminently upon approval of Amneal's ANDA.

439. 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 '874 patent under 35 U.S.C. § 271(a).

440. 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 '874 patent.

441. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of the ’874 patent when Amneal’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

442. Upon information and belief, Amneal knows that Amneal’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’874 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 ’874 patent immediately and imminently upon approval of the Amneal’s ANDA.

443. The foregoing actions by Amneal constitute and/or would constitute infringement of the ’874 patent, active inducement of infringement of the ’874 patent and/or contribution to the infringement by others of the ’874 patent.

444. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the ’874 patent, actively inducing infringement of the ’874 patent and/or contributing to the infringement by others of the ’874 patent.

445. 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.

446. 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. 9,402,874 BY AMNEAL**

447. The allegations of the proceeding paragraphs 1-446 are realleged and incorporated herein by reference.

448. 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.

449. Such conduct will lead to direct infringement of one or more claims on the '874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '874 patent under 35 U.S.C. § 271(c).

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

451. 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 '874 patent. Amneal's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

452. Upon information and belief, Amneal will knowingly and willfully infringe the '874 patent.

453. Teva will be irreparably harmed if Amneal is not enjoined from infringing the '874 patent.

**COUNT XI FOR INFRINGEMENT OF U.S. PATENT NO. 9,402,874 BY BIOCON**

454. The allegations of the proceeding paragraphs 1-453 are realleged and incorporated herein by reference.

455. Before filing of this action, the ’874 patent was listed in the Orange Book with respect to Teva’s COPAXONE® 40 mg/mL product.

456. The use of Biocon’s Glatiramer Acetate Product according to its labeling and prescribing information is covered by one or more claims of the ’874 patent.

457. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Biocon’s Glatiramer Acetate Product would infringe one or more claims of the ’874 patent.

458. Under 35 U.S.C. § 271(e)(2)(A), Biocon’s submission to the FDA of the Amneal ANDA with a Paragraph IV Certification to obtain approval for Amneal’s Glatiramer Acetate Product before the expiration of the ’874 patent constitutes, or will constitute, an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Biocon’s Glatiramer Acetate Product would infringe one or more claims of the ’874 patent.

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

460. Upon information and belief, Biocon plans and intends to, and will, infringe the ’874 patent immediately and imminently upon approval of Biocon’s ANDA.

461. Upon information and belief, immediately and imminently upon approval of Biocon's ANDA, Biocon's Glatiramer Acetate Product will be administered according to its labeling and prescribing information causing direct infringement of the claims of the '874 patent under 35 U.S.C. § 271(a).

462. Upon information and belief, Biocon, 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 '874 patent.

463. Upon information and belief, Biocon plans and intends to, and will, actively induce infringement of the '874 patent when Biocon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

464. Upon information and belief, Biocon knows that Biocon's Glatiramer Acetate Product is especially made or adapted for use in infringing the '874 patent and that Biocon's Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Biocon, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '874 patent immediately and imminently upon approval of the Biocon's ANDA.

465. The foregoing actions by Biocon constitute and/or would constitute infringement of the '874 patent, active inducement of infringement of the '874 patent and/or contribution to the infringement by others of the '874 patent.

466. Upon information and belief, Biocon acted without a reasonable basis for believing that it would not be liable for infringing the '874 patent, actively inducing infringement of the '874 patent and/or contributing to the infringement by others of the '874 patent.

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

468. Biocon'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 XII FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 9,402,874 BY BIOCON**

469. The allegations of the proceeding paragraphs 1-468 are realleged and incorporated herein by reference.

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

471. Such conduct will lead to direct infringement of one or more claims on the '874 patent under 35 U.S.C. § 271(a), constitute inducement of infringement of the '874 patent under 35 U.S.C. § 271(b), and constitute contributory infringement of the '874 patent under 35 U.S.C. § 271(c).

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

473. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Biocon as to liability for the infringement of the '874 patent. Biocon's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Biocon's threatened imminent actions.

474. Upon information and belief, Biocon will knowingly and willfully infringe the '874 patent.

475. Teva will be irreparably harmed if Biocon is not enjoined from infringing the '874 patent.

## PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

**Against all Defendants**

(a) a judgment that the '874 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 with a Paragraph IV Certification was an act of infringement of one or more claims of the '874 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 '874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '874 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 ’874 patent, shall be a date that is not earlier than the expiration of the ’874 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 ’874 patent, or inducing or contributing to the infringement of the ’874 patent until after the expiration of the ’874 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 ’874 patent, or inducing or contributing to the infringement of the ’874 patent, until after the expiration of the ’874 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 ’874 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 ’874 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’874 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 with a Paragraph IV Certification was an act of infringement of one or more claims of the '874 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 '874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '874 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 '874 patent, shall be a date that is not earlier than the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent until after the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent, until after the expiration of the '874 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 '874 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 '874 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '874 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 with a Paragraph IV Certification was an act of infringement of one or more claims of the '874 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 '874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '874 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 '874 patent, shall be a date that is not earlier than the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent until after the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent, until after the expiration of the '874 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 '874 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 '874 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '874 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 with a Paragraph IV Certification was an act of infringement of one or more claims of the '874 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 '874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '874 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 '874 patent, shall be a date that is not earlier than the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent until after the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent, until after the expiration of the '874 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 '874 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 '874 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '874 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 with a Paragraph IV Certification was an act of infringement of one or more claims of the '874 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 '874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '874 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 '874 patent, shall be a date that is not earlier than the expiration of the '874 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's Glatiramer Acetate Product, or any product the use of which infringes the '874 patent, or inducing or contributing to the infringement of the '874 patent until after the expiration of the '874 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 '874 patent, or inducing or contributing to the infringement of the '874 patent, until after the expiration of the '874 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 '874 patent;

(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 '874 patent, or the inducement or

contribution of the foregoing, prior to the expiration of the ’874 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

**Against Biocon**

(ii) a judgment that Biocon’s submission of ANDA No. 209001 with a Paragraph IV Certification was an act of infringement of one or more claims of the ’874 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Biocon’s Glatiramer Acetate Product prior to the expiration of the ’874 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’874 patent;

(jj) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Biocon ANDA No. 209001 or any product the use of which infringes the ’874 patent, shall be a date that is not earlier than the expiration of the ’874 patent;

(kk) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Biocon and all persons acting in concert with Biocon from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Biocon’s Glatiramer Acetate Product, or any product the use of which infringes the ’874 patent, or inducing or contributing to the infringement of the ’874 patent until after the expiration of the ’874 patents;

(ll) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Biocon and all persons acting in concert with Biocon from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Biocon’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’874 patent, or inducing or contributing to the infringement of the ’874 patent, until after the expiration of the ’874 patent;

(mm) an Order enjoining Biocon and all persons acting in concert with Biocon from seeking, obtaining, or maintaining approval of the Biocon ANDA No. 209001 before the expiration of the '874 patent; and

(nn) an award of Teva's damages or other monetary relief to compensate Teva if Biocon engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Biocon's Glatiramer Acetate Product, or any product or compound the use of which infringes the '874 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '874 patent in accordance with 35 U.S.C. § 271(e)(4)(C).

*/s/ Karen E. Keller*

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