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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, DAIICHI SANKYO CO., LTD., DAIICHI SANKYO, INC., and UBE INDUSTRIES, LTD.,	)	**C.A. NO. _____**
Plaintiffs,	)	
v.	)	
ACCORD HEALTHCARE, INC. USA, ACCORD HEALTHCARE, INC., INTAS PHARMACEUTICALS LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL PHARMACEUTICALS CO. INDIA PVT. LTD., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S	)	

LABORATORIES, INC., GLENMARK GENERICS INC., USA, GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS LTD., HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT V, HETERO DRUGS LTD., MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, PAR PHARMACEUTICAL COMPANIES, INC., PAR PHARMACEUTICAL, INC., SUN PHARMA GLOBAL FZE, CARACO PHARMACEUTICAL LABORATORIES, LTD., SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., WATSON LABORATORIES, INC., ACTAVIS PLC, ACTAVIS, INC., ACTAVIS PHARMA, INC., ZYDUS PHARMACEUTICALS USA, INC., CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA),

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Eli Lilly and Company; Daiichi Sankyo Co., Ltd.; Daiichi Sankyo, Inc.; and Ube Industries, Ltd. ("Plaintiffs"), for their Complaint against defendants Accord Healthcare, Inc. USA; Accord Healthcare, Inc.; Intas Pharmaceuticals Ltd. (collectively "Accord"); Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals of New York, LLC; Amneal Pharmaceuticals Co. India Pvt. Ltd. (collectively "Amneal"); Aurobindo Pharma Limited; Aurobindo Pharma USA Inc. (collectively "Aurobindo"); Dr. Reddy's Laboratories, Ltd; Dr. Reddy's Laboratories, Inc. (collectively "DRL"); Glenmark Generics Inc., USA; Glenmark Generics Ltd.; Glenmark Pharmaceuticals Ltd. (collectively "Glenmark"); Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit V; Hetero Drugs Ltd. (collectively "Hetero"); Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan Laboratories Limited (collectively "Mylan"); Par Pharmaceutical Companies, Inc.; Par Pharmaceutical, Inc. (collectively "Par Pharmaceutical"); Sun Pharma Global FZE, Caraco Pharmaceutical Laboratories, Ltd.; Sun Pharma Global Inc.; Sun Pharmaceutical Industries, Ltd. (collectively "Sun"); Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd. (collectively "Teva"); Watson Laboratories, Inc.; Actavis plc; Actavis, Inc.; Actavis Pharma, Inc. (collectively "Watson"); Zydus Pharmaceuticals USA, Inc.; and Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (collectively " Zydus") ("Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Eli Lilly and Company ("Lilly") is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

2. Plaintiff Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") is a corporation organized and existing under the laws of Japan and has a principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

3. Plaintiff Daiichi Sankyo, Inc. ("DSI") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

4. DSI is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc., which is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

5. Daiichi Sankyo U.S. Holdings, Inc. is a wholly-owned subsidiary of Daiichi Sankyo.

6. Plaintiff Ube Industries, Ltd. ("Ube") is a corporation organized and existing under the laws of Japan and has a principal place of business at 1978-96, Kogushi, Ube, Yamaguchi 755-8633, Japan.

7. Defendant Accord Healthcare, Inc. USA ("Accord USA") is a corporation organized and existing under the laws of the State of North Carolina and has a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

8. Defendant Accord Healthcare, Inc. ("AHI") is a corporation organized and existing under the laws of the State of North Carolina and has a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

9. Defendant Intas Pharmaceuticals, Ltd. ("Intas") is a corporation organized and existing under the laws of India and has a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

10. Accord USA and AHI are wholly-owned subsidiaries of Intas.

11. The acts of Accord USA complained of herein were done with the cooperation, participation, and assistance of AHI and Intas.

12. Defendant Amneal Pharmaceuticals LLC ("Amneal Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, NJ, 08807-2477. Amneal Pharmaceuticals is registered to do business in the State of New Jersey.

13. Defendant Amneal Pharmaceuticals of New York, LLC ("Amneal New York") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 85 Adams Avenue, Hauppauge, New York 11788.

14. Defendant Amneal Pharmaceuticals Co. India Pvt. Ltd. ("Amneal India") is a corporation organized and existing under the laws of India and has a principal place of business at 882/1-871, Near Hotel Kankavati, Village Rajoda, Bavla Taluka, Ahmedabad-382220, Gujarat, India.

15. Amneal New York and Amneal India are both wholly-owned subsidiaries of Amneal Pharmaceuticals.

16. The acts of Amneal Pharmaceuticals complained of herein were done with the cooperation, participation, and assistance of Amneal New York and Amneal India.

17. Defendant Aurobindo Pharma Limited ("Aurobindo Ltd.") is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

18. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

19. Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

20. The acts of Aurobindo Ltd. complained of herein were done with the cooperation, participation, and assistance of Aurobindo USA.

21. Defendant Dr. Reddy's Laboratories, Ltd. ("DRLL") is a corporation organized and existing under the laws of India and has a principal place of business at 8-2-337, Road no. 3, Banjara Hills, Hyderabad, 500 034, India.

22. Defendant Dr. Reddy's Laboratories, Inc. ("DRLI") is a corporation organized and existing under the laws of the State of New Jersey and has a principal place of business at 107 College Road East, Princeton, NJ 08540. DRLI is registered to do business in the State of New Jersey.

23. DRLI is a wholly-owned subsidiary of DRLL.

24. Defendant Glenmark Generics Inc., USA ("Glenmark USA") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

25. Defendant Glenmark Generics Ltd. ("GGL") is a corporation organized and existing under the laws of India and has a principal place of business at Glenmark House, HDO-Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India.

26. Defendant Glenmark Pharmaceuticals Ltd. ("GPL") is a corporation organized and existing under the laws of India and has a principal place of business at Glenmark House, HDO-Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India.

27. Glenmark USA is a wholly-owned subsidiary of GGL.

28. GGL is a wholly-owned subsidiary of GPL.

29. The acts of GGL complained of herein were done with the cooperation, participation, and assistance of Glenmark USA and GPL.

30. Defendant Hetero USA Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is registered to do business in the State of New Jersey.

31. Defendant Hetero Labs Limited ("Hetero Labs") is a corporation organized and existing under the laws of India and has a principal place of business at 22-110, IDA, Jeedimetla, Hyderabad-500055.

32. Defendant Hetero Labs Limited Unit V ("Hetero V") is a corporation organized and existing under the laws of India and has a principal place of business at Survey No. 439, 440, 441 & 458, APIIC Formulation SEZ, Polepally Village, Jadcherla, Mahaboob Nagar Dist-509 301, Andhra Pradesh, India.

33. Defendant Hetero Drugs Ltd. ("Hetero Drugs") is a corporation organized and existing under the laws of India and has a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018, Andhra Pradesh, India.

34. Hetero USA is a wholly-owned subsidiary of Hetero Labs.

35. Hetero V is a division of Hetero Labs.

36. Hetero USA acts as the agent of Hetero Labs and Hetero V.

37. The acts of Hetero USA complained of herein were done with the cooperation, participation, and assistance of Hetero Labs, Hetero V and Hetero Drugs.

38. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized and existing under the laws of the State of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

39. Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania and has a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

40. Defendant Mylan Laboratories Limited ("Mylan Labs") is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

41. Mylan and Mylan Labs are wholly-owned subsidiaries of Mylan Inc.

42. The acts of Mylan Pharms. complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

43. Defendant Par Pharmaceutical Companies, Inc. ("Par Pharmaceutical Companies") is a corporation organized and existing under the laws of Delaware and has a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Par Pharmaceutical Companies is registered to do business in the State of New Jersey.

44. Defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of Delaware and has a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Par is registered to do business in the State of New Jersey.

45. Par is a wholly-owned subsidiary of Par Pharmaceutical Companies.

46. Par Pharmaceutical Companies operates primarily through its wholly-owned subsidiary Par.

47. The acts of Par complained of herein were done with the cooperation, participation, and assistance of Par Pharmaceutical Companies.

48. Defendant Sun Pharma Global FZE ("Sun FZE") is a corporation organized and existing under the laws of the United Arab Emirates and has a principal place of business at Suite 4 43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. Sun FZE, itself and through its agent Caraco, sells various drug products in the United States, including this judicial district.

49. Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a corporation organized and existing under the laws of the State of Michigan and has a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

50. Sun Pharmaceuticals Industries, Inc. was a corporation organized and existing under the laws of the State of Michigan and had a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. Sun Pharmaceuticals Industries, Inc. merged into Caraco on or about February 28, 2013, with Caraco as the surviving corporation. Sun Pharmaceuticals, Inc. was registered to do business in this district. Sun Pharmaceuticals, Inc. sold and Caraco sells various drug products in the United States, including in this district.

51. Defendant Sun Pharma Global Inc. ("Sun Pharma") is a corporation organized and existing under the laws of the British Virgin Islands and has a principal place of business at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands.

52. Defendant Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") is a corporation organized and existing under the laws of India and has a principal place of business at Acme Plaza, Andheri Kurla Rd., Andheri East, Mumbai 400059, Maharashtra, India.

53. Sun FZE is a wholly owned subsidiary of Sun Pharma, which in turn is a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd.

54. Caraco is a wholly owned-subsidiary of Sun Pharmaceutical Industries, Ltd.

55. The acts of Sun FZE complained of herein were done with the cooperation, participation, and assistance of Caraco, Sun Pharma, and Sun Ltd.

56. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

57. Defendant Teva Pharmaceutical Industries, Ltd. ("TPIL") is a corporation organized and existing under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

58. Teva USA is a wholly-owned subsidiary of TPIL.

59. The acts of Teva USA complained of herein were done with the cooperation, participation, and assistance of TPIL.

60. Defendant Watson Laboratories, Inc. ("Watson Labs") is a corporation organized and existing under the laws of the State of Nevada and has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

61. Defendant Actavis plc is a corporation organized and existing under the laws of Ireland and has a principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

62. Defendant Actavis, Inc. ("Actavis") (formerly known as Watson Pharmaceuticals, Inc.) is a corporation organized and existing under the laws of the State of Nevada and has a principal place of business at Morris Corporate Center III, 400

Interpace Parkway, Parsippany, New Jersey 07054. Actavis is registered to do business in the State of New Jersey.

63. Defendant Actavis Pharma, Inc. ("Actavis Pharma") (formerly known as Watson Pharma, Inc.) is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis Pharma is registered to do business in the State of New Jersey.

64. Watson Labs and Actavis Pharma are wholly-owned subsidiaries of Actavis.

65. Actavis is a wholly-owned subsidiary of Actavis plc.

66. The acts of Watson Labs complained of herein were done with the cooperation, participation, and assistance of Actavis plc, Actavis, and Actavis Pharma.

67. Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus USA") is a corporation organized and existing under the laws of the State of New Jersey and has a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus USA is registered to do business in the State of New Jersey.

68. Defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Zydus Cadila") is a corporation organized and existing under the laws of India and has a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

69. Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

70. The acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Cadila.

NATURE OF THE ACTION

71. This is a civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, arising out of the filing by Defendants of Abbreviated New Drug Applications ("ANDA"s) with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Lilly's pharmaceutical products, Effient® 5mg and 10mg tablets, prior to the expiration of Daiichi Sankyo's and Ube's United States Patent No. 5,288,726 by Mylan and Nos. 8,404,703 and 8,569,325 by all Defendants, which cover Effient® 5mg and 10mg tablets and/or methods of using Effient® products and are exclusively licensed to Lilly.

JURISDICTION AND VENUE

72. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

73. This Court has personal jurisdiction over Accord USA because of Accord USA's continuous and systematic contacts with this State. Accord USA (1) intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State.

74. This Court has personal jurisdiction over AHI because AHI (1) intentionally markets and provides pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device manufacturer in this State, and (3) enjoys substantial

income from sales of its generic pharmaceutical products in this State. AHI has previously submitted to personal jurisdiction in this judicial district.

75. This Court has personal jurisdiction over Intas because Intas (1) is the parent company of Accord USA and AHI, (2) operates through its wholly owned subsidiary Accord USA, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Intas has previously submitted to personal jurisdiction in this judicial district.

76. This Court has personal jurisdiction over Amneal Pharmaceuticals because Amneal Pharmaceuticals has continuous and systematic contacts with this State. Amneal Pharmaceuticals (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) has appointed an agent for service of process in this State (4) intentionally markets and provides its generic pharmaceutical products to residents of this State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device manufacturer in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. Amneal Pharmaceuticals has previously submitted to personal jurisdiction in this judicial district.

77. This Court has personal jurisdiction over Amneal New York because it has continuous and systematic contacts with this State. Amneal New York (1) intentionally markets and provides its generic pharmaceutical products to residents of this

State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State. Amneal New York has previously submitted to personal jurisdiction in this judicial district.

78. This Court has personal jurisdiction over Amneal India because Amneal India (1) intentionally markets and provides pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State. Amneal India has previously submitted to personal jurisdiction in this judicial district.

79. This Court has personal jurisdiction over Aurobindo Ltd. because Aurobindo Ltd. has continuous and systematic contacts with this State. Aurobindo Ltd. (1) intentionally markets and provides its generic pharmaceutical products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State. Aurobindo Ltd. has previously submitted to personal jurisdiction in this judicial district.

80. This Court has personal jurisdiction over Aurobindo USA because it has its principal place of business in the State of New Jersey and has continuous and systematic contacts with this State. Aurobindo USA (1) has its principal place of business in New Jersey, (2) is registered to do business in this State, (3) has appointed an agent for service of process in this state, (4) intentionally markets and provides its generic pharmaceutical products to residents of this State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device

wholesaler in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. Aurobindo USA has previously submitted to personal jurisdiction in this judicial district.

81. This Court has personal jurisdiction over DRLL because of DRLL's continuous and systematic contacts with this State. DRLL (1) intentionally markets and provides its generic pharmaceutical products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State. DRLL has previously submitted to personal jurisdiction in this judicial district.

82. This Court has personal jurisdiction over DRLI because DRLI is incorporated in New Jersey and has continuous and systematic contacts with this State. DRLI (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) has appointed an agent for service of process in this State, (4) intentionally markets and provides its generic pharmaceutical products to residents of this State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device wholesaler in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. DRLI has previously submitted to personal jurisdiction in this judicial district.

83. This Court has personal jurisdiction over Glenmark USA because of Glenmark USA's continuous and systematic contacts with this State. Glenmark USA (1) has its principal place of business in this State, (2) is registered to do business in the State of New Jersey, (3) has appointed an agent for service of process in this State, (4)

intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device wholesaler in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. Glenmark USA has previously submitted to personal jurisdiction in this judicial district.

84. This Court has personal jurisdiction over GGL because GGL (1) is the parent company of Glenmark USA, (2) operates through its wholly owned subsidiary Glenmark USA, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

85. This Court has personal jurisdiction over GPL because GPL (1) is the parent company of GGL, (2) operates through its wholly owned subsidiary GGL, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. GPL has previously submitted to personal jurisdiction in this judicial district.

86. This Court has personal jurisdiction over Hetero USA because Hetero USA has continuous and systematic contacts with this State. Hetero USA (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) has appointed an agent for service of process in this State (4) intentionally markets and provides its generic pharmaceutical products to residents of this

State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device wholesaler in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. Hetero USA has previously submitted to personal jurisdiction in this judicial district.

87. This Court has personal jurisdiction over Hetero Labs because it has continuous and systematic contacts with this State. Hetero Labs (1) is the parent company of Hetero USA, (2) operates through its wholly owned subsidiary Hetero USA, (3) intentionally markets and provides its generic pharmaceutical products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Hetero Labs has previously submitted to personal jurisdiction in this judicial district.

88. This Court has personal jurisdiction over Hetero V because it has continuous and systematic contacts with this State. Hetero V (1) is a division of Hetero Labs, (2) operates through its agent Hetero USA, (3) intentionally markets and provides its generic pharmaceutical products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

89. This Court has personal jurisdiction over Hetero Drugs because it has continuous and systematic contacts with this State. Hetero Drugs (1) is a division of Hetero Labs, (2) operates through its agent Hetero USA, (3) intentionally markets and provides its generic pharmaceutical products to residents of this State, (4) maintains a

broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

90. This Court has personal jurisdiction over Mylan Pharms. because Mylan's Pharms. has continuous and systematic contacts with this State. Mylan Pharms. (1) is registered to do business in the State of New Jersey, (2) has appointed an agent for service of process in this State, (3) intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Mylan Pharms. has previously submitted to personal jurisdiction in this judicial district.

91. This Court has personal jurisdiction over Mylan Inc. because Mylan Inc. (1) is registered to do business in the state of New Jersey (2) has appointed an agent for service of process in this State, (3) is the parent of Mylan, (4) operates through its wholly owned subsidiary Mylan Pharms., (5) intentionally markets and provides pharmaceutical drug products to residents of this State, (6) maintains a broad distributorship network within this State, and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State. Mylan Inc. has previously submitted to personal jurisdiction in this judicial district.

92. This Court has personal jurisdiction over Mylan Labs because Mylan Labs (1) intentionally markets and provides pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys

substantial income from sales of its generic pharmaceutical products in this State. Mylan Labs has previously submitted to personal jurisdiction in this judicial district.

93. This Court has personal jurisdiction over Par because its principal place of business is in New Jersey and because it has continuous and systematic contacts with this State. Par (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) intentionally markets and provides its generic pharmaceutical products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Par has previously submitted to personal jurisdiction in this judicial district.

94. This Court has personal jurisdiction over Par Pharmaceutical Companies because its principal place of business is in New Jersey and because it has continuous and systematic contacts with the State. Par Pharmaceutical Companies (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) is the parent company of Par, (4) operates primarily through its wholly owned subsidiary Par, and (5) shares common headquarters and officers and directors with Par. Par Pharmaceutical Companies has previously submitted to personal jurisdiction in this judicial district.

95. This Court has personal jurisdiction over Sun FZE because Sun FZE has continuous and systematic contacts with this State. Sun FZE (1) intentionally markets and provides its generic pharmaceutical products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from

sales of its generic pharmaceutical products in this State. Sun FZE has previously submitted to personal jurisdiction in this judicial district.

96. This Court has personal jurisdiction over Caraco because Caraco (1) is registered to do business in the State of New Jersey, (2) has appointed an agent for service of process in this State, (3) intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Caraco has previously submitted to personal jurisdiction in this judicial district.

97. This Court has personal jurisdiction over Sun Pharma because Sun Pharma (1) is the parent company of Sun FZE, (2) operates through its wholly owned subsidiary Sun FZE, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Sun Pharma has previously submitted to personal jurisdiction in this judicial district.

98. This Court has personal jurisdiction over Sun Ltd. because Sun Ltd. (1) is the parent company of Sun FZE, Sun Pharma and Caraco (2) operates through its wholly owned subsidiaries Sun FZE, Sun Pharma and Caraco, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of

its generic pharmaceutical products in this State. Sun Ltd. has previously submitted to personal jurisdiction in this judicial district.

99. This Court has personal jurisdiction over Teva USA because of Teva USA's continuous and systematic contacts with this State. Teva USA (1) is registered to do business in the State of New Jersey, (2) has appointed an agent for service of process in this State, (3) intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device wholesaler in this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Teva USA has previously submitted to personal jurisdiction in this judicial district.

100. This Court has personal jurisdiction over TPIL because TPIL (1) is the parent of Teva USA, (2) operates through its wholly owned subsidiary Teva USA, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. TPIL has previously submitted to personal jurisdiction in this judicial district.

101. This Court has personal jurisdiction over Watson Labs because its principal place of business is in New Jersey and because it has continuous and systematic contacts with this State. Watson Labs (1) has its principal place of business in New Jersey, (2) intentionally markets and provides its generic pharmaceutical products to residents of this State, (3) maintains a broad distributorship network within this State, and

(4) enjoys substantial income from sales of its generic pharmaceutical products in this State. Watson Labs has previously submitted to personal jurisdiction in this judicial district.

102. This Court has personal jurisdiction over Actavis plc because Actavis plc (1) is the parent company of Watson Labs, (2) operates through its wholly owned subsidiary Watson Labs, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, (5) enjoys substantial income from sales of its generic pharmaceutical products in this State, and (6) shares common officers and directors with Watson Labs.

103. This Court has personal jurisdiction over Actavis because Actavis (1) is the parent company of Watson Labs, (2) operates through its wholly owned subsidiary Watson Labs, (3) intentionally markets and provides pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, (5) enjoys substantial income from sales of its generic pharmaceutical products in this State, (6) is registered with the Secretary of State to do business in this State, (7) has appointed an agent for service of process in this State, and (8) shares common officers and directors with Watson Labs.

104. This Court has personal jurisdiction over Actavis Pharma because Actavis Pharma (1) intentionally markets and provides pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State, (3) enjoys substantial income from sales of its generic pharmaceutical products in this State, (4) is registered with the Secretary of State to do business in this State, (5) has appointed an

agent for service of process in this State, and (6) shares common officers and directors with Watson Labs.

105. This Court has personal jurisdiction over Zydus USA because Zydus USA is incorporated in New Jersey and has continuous and systematic contacts with this State. Zydus USA (1) has its principal place of business in New Jersey, (2) is registered to do business in the State of New Jersey, (3) has appointed an agent for service of process in this State (4) intentionally markets and provides its generic pharmaceutical products to residents of this State, (5) maintains a broad distributorship network within this State and is registered as a Wholesale Drug & Medical Device wholesaler in this State, and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State. Zydus USA has previously submitted to personal jurisdiction in this judicial district.

106. This Court has personal jurisdiction over Zydus Cadila because it has continuous and systematic contacts with this State. Zydus Cadila (1) is the parent company of Zydus USA, (2) operates through its wholly owned subsidiary Zydus USA, (3) intentionally markets and provides its generic pharmaceutical products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State. Zydus Cadila has previously submitted to personal jurisdiction in this judicial district.

107. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

108. On March 12, 2014, Plaintiffs filed a Complaint against Defendants for patent infringement in the United States District Court for the Southern District of

Indiana. The resulting action, Civ. Action No. 1:14-cv-00389-TWP-DKL ("the Indiana Effient® Action") is presently pending. A copy of the Complaint in the Indiana Effient® Action, excluding exhibits, is attached hereto as Appendix A. The Indiana Complaint alleges essentially the same acts of infringement as the present Complaint.

109. Based on Defendant's continuous and systematic business contacts with Indiana, Defendants should be subject to personal jurisdiction in the Southern District of Indiana; however, Defendants may assert that Defendants are not subject to such jurisdiction.

110. Plaintiffs are therefore filing the instant Complaint, which has identical infringement claims against Defendants as the Indiana Effient® Action, a so-called Hatch-Waxman "protective suit," to preserve its right for a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii).

THE PATENTS-IN-SUIT

111. On February 22, 1994, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 5,288,726 ("the '726 patent"), entitled "Tetrahydrothienopyridine Derivatives, Furo and Pyrrolo Analogs Thereof and Their Preparation and Uses for Inhibiting Blood Platelet Aggregation." The '726 patent is assigned to Ube and Sankyo Company, Limited (subsequently known as Daiichi Sankyo). A copy of the '726 patent is attached as Appendix B.

112. On March 26, 2013, the USPTO duly and legally issued United States Patent No. 8,404,703 ("the '703 patent"), entitled "Medicinal Compositions Containing Aspirin." The '703 patent is assigned to Daiichi Sankyo and Ube. A copy of the '703 patent is attached as Appendix C.

113. On October 29, 2013, the USPTO duly and legally issued United States Patent No. 8,569,325 ("the '325 patent"), entitled "Method of Treatment with Coadministration of Aspirin and Prasugrel." The '325 patent is assigned to Daiichi Sankyo and Ube. A copy of the '325 patent is attached as Appendix D.

FACTUAL BACKGROUND

Effient® Products

114. Lilly is an exclusive licensee to the '726 patent, which covers the active ingredient in Effient® products, and the '703 and '325 patents, which cover methods of using Effient® products.

115. Effient® products were approved by the FDA for the reduction of thrombotic cardiovascular events in certain patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI, or angioplasty).

116. Effient® products contain prasugrel hydrochloride, which is known as 5-[(1RS)-2-cyclopropyl-1-(2-fluorophenyl)-2-oxoethyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridin-2-yl acetate hydrochloride or 2-acetoxy-5-(α-cyclopropylcarbonyl-2-fluorobenzy1)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine hydrochloride, and is covered by the '726 patent.

117. Effient® products are formulated in two strengths, EQ 5 mg or EQ 10 mg base of prasugrel hydrochloride, where the EQ 10 mg base dose is the reference listed drug.

118. The instructions accompanying Effient® products state that patients taking Effient® products should also take aspirin.

119. The use of Effient® products in combination with aspirin for the reduction of thrombotic cardiovascular events in patients with ACS who are to be managed with PCI is covered by the claims of the '703 and '325 patents.

120. According to the instructions accompanying Effient®, the clinical evidence for the effectiveness of Effient® is derived from the TRITON-TIMI 38 study, which compared Effient® to a regimen of clopidogrel, each added to aspirin.

121. Lilly holds an approved New Drug Application, No. 22-307, for the manufacture and sale of Effient® products, 5 mg and 10 mg prasugrel hydrochloride tablets, in the United States (the "Effient® NDA").

122. Lilly currently markets Effient® products in the United States.

123. DSI currently co-promotes Effient® products in the United States with Lilly.

124. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '726, '703 and '325 patents are listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), as covering Effient® products.

Infringement by Accord

125. Accord USA has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205987 (the "Accord ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Accord Products") in the United States.

126. The active ingredient and strength of the Accord Products are 5 mg and 10 mg EQ base of prasugrel hydrochloride.

127. On or about February 12, 2014, Accord USA sent Lilly and Daiichi Sankyo a letter, dated February 12, 2014, and an attached memorandum (collectively, the "Accord Notification") stating that Accord USA had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Accord Products in the United States ("Accord Paragraph IV Certification").

128. Accord USA did not send Ube the Accord Notification.

129. The prasugrel hydrochloride active ingredient in the Accord Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

130. The Accord ANDA refers to and relies upon the Effient® NDA and contains data that, according to Accord USA, demonstrates that the Accord Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

131. Accord USA will knowingly accompany the Accord Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Accord Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4) and (8).

132. Accord USA knows that the instructions that will accompany the Accord Products will induce and/or contribute to others using the Accord Products in the manner set forth in the instructions.

133. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Accord Products in accordance with the instructions provided by Accord USA, after the FDA approves the Accord ANDA.

134. Accord USA specifically intends that physicians, health care providers, and/or patients will use the Accord Products in accordance with the instructions provided by Accord USA to directly infringe one or more claims of the '703 and '325 patents. Accord USA therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

135. Accord USA knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Accord Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

136. Accord USA designed the Accord Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Accord Products to use the Accord Products in a way that would infringe the '703 and '325 patents.

137. AHI and Intas were actively involved in the preparation and/or submission of the Accord ANDA including the Accord Paragraph IV Certification against the '703 and '325 patents.

138. AHI and Intas actively and knowingly provided Accord USA with material information and support in preparing and submitting the Accord ANDA and have therefore aided and/or abetted in the filing of the Accord ANDA.

139. The Accord Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

140. Unless Accord is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Accord's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

141. Plaintiffs commenced this action within 45 days of the date of the Accord Notification.

COUNT I: INFRINGEMENT BY ACCORD OF U.S. PATENT NO. 8,404,703

142. Accord USA's filing of the Accord ANDA containing the Accord Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Accord Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

143. AHI and Intas actively and knowingly aided, abetted, and induced Accord USA to submit the Accord ANDA containing the Accord Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

144. After the FDA approves the Accord ANDA, Accord USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the

Accord Products in the United States, import either or both of the Accord Products into the United States, and/or induce such acts during the term of the '703 patent.

145. Accord USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Accord ANDA is approved.

146. AHI and Intas have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

147. Accord USA lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Accord ANDA and made the Accord Paragraph IV Certification. Accordingly, the Accord Paragraph IV Certification was wholly unjustified.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT BY ACCORD OF U.S. PATENT NO. 8,404,703

148. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

149. Accord USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Accord ANDA is approved.

150. AHI and Intas have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT III: INFRINGEMENT BY ACCORD OF U.S. PATENT NO. 8,569,325

151. Accord USA's filing of the Accord ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Accord Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

152. AHI and Intas actively and knowingly aided, abetted, and induced Accord USA to submit the Accord ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

153. If the FDA approves the Accord ANDA, Accord USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Accord Products in the United States, import either or both of the Accord Products into the United States, and/or induce such acts during the term of the '325 patent.

154. Accord USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Accord ANDA is approved.

155. AHI and Intas have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

156. Accord USA lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Accord ANDA and made the Accord Paragraph IV Certification. Accordingly, the Accord Paragraph IV Certification was wholly unjustified.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT BY ACCORD OF U.S. PATENT NO. 8,569,325

157. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

158. Accord USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Accord ANDA is approved.

159. AHI and Intas have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Amneal

160. Amneal Pharmaceuticals has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205913 (the "Amneal ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Amneal Products") in the United States.

161. The active ingredient and strength of the Amneal Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

162. On or about February 12, 2014, Amneal Pharmaceuticals sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 12, 2014, and an attached memorandum (collectively, the "Amneal Notification") stating that Amneal Pharmaceuticals had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Amneal Products in the United States ("Amneal Paragraph IV Certification").

163. The prasugrel hydrochloride active ingredient in the Amneal Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

164. The Amneal ANDA refers to and relies upon the Effient® NDA and contains data that, according to Amneal Pharmaceuticals, demonstrates that the Amneal Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

165. Amneal Pharmaceuticals will knowingly accompany the Amneal Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Amneal Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

166. Amneal Pharmaceuticals knows that the instructions that will accompany the Amneal Products will induce and/or contribute to others using the Amneal Products in the manner set forth in the instructions.

167. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Amneal Products in accordance with the instructions provided by Amneal Pharmaceuticals, after the FDA approves the Amneal ANDA.

168. Amneal Pharmaceuticals specifically intends that physicians, health care providers, and/or patients will use the Amneal Products in accordance with the instructions provided by Amneal Pharmaceuticals to directly infringe one or more claims of the '703 and '325 patents. Amneal Pharmaceuticals therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

169. Amneal Pharmaceuticals knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Amneal Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

170. Amneal Pharmaceuticals designed the Amneal Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Amneal Products to use the Amneal Products in a way that would infringe the '703 and '325 patents.

171. Amneal New York and Amneal India were actively involved in the preparation and/or submission of the Amneal ANDA including the Amneal Paragraph IV Certification against the '703 and '325 patents.

172. Amneal New York and Amneal India actively and knowingly provided Amneal Pharmaceuticals with material information and support in preparing and submitting the Amneal ANDA and have therefore aided and/or abetted in the filing of the Amneal ANDA.

173. The Amneal Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

174. Unless Amneal is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Amneal's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

175. Plaintiffs commenced this action within 45 days of receiving the Amneal Notification.

COUNT V: INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,404,703

176. The filing by Amneal Pharmaceuticals of the Amneal ANDA containing the Amneal Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Amneal Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

177. Amneal New York and Amneal India actively and knowingly aided, abetted, and induced Amneal Pharmaceuticals to submit the Amneal ANDA containing the Amneal Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

178. After the FDA approves the Amneal ANDA, Amneal Pharmaceuticals plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Amneal Products in the United States, import either or both of the Amneal Products into the United States, and/or induce such acts during the term of the '703 patent.

179. Amneal Pharmaceuticals has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Amneal ANDA is approved.

180. Amneal New York and Amneal India have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

181. Amneal Pharmaceuticals lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Amneal ANDA and made the Amneal Paragraph IV Certification. Accordingly, the Amneal Paragraph IV Certification was wholly unjustified.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,404,703

182. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

183. Amneal Pharmaceuticals has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Amneal ANDA is approved.

184. Amneal New York and Amneal India have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT VII: INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,569,325

185. The filing by Amneal Pharmaceuticals of the Amneal ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Amneal Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

186. Amneal New York and Amneal India actively and knowingly aided, abetted, and induced Amneal Pharmaceuticals to submit the Amneal ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

187. If the FDA approves the Amneal ANDA, Amneal Pharmaceuticals plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Amneal Products in the United States, import either or both of the Amneal Products into the United States, and/or induce such acts during the term of the '325 patent.

188. Amneal Pharmaceuticals has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Amneal ANDA is approved.

189. Amneal New York and Amneal India have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

190. Amneal Pharmaceuticals lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Amneal ANDA and made the Amneal Paragraph IV

Certification. Accordingly, the Amneal Paragraph IV Certification was wholly unjustified.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,569,325

191. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

192. Amneal Pharmaceuticals has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Amneal ANDA is approved.

193. Amneal New York and Amneal India have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Aurobindo

194. Aurobindo Ltd. has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205888 (the "Aurobindo ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Aurobindo Products") in the United States.

195. The active ingredient and strength of the Aurobindo Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

196. On or about February 12, 2014, Aurobindo Ltd. sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 12, 2014, and an attached memorandum

(collectively, the "Aurobindo Notification") stating that Aurobindo Ltd. had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Aurobindo Products in the United States ("Aurobindo Paragraph IV Certification").

197. The prasugrel hydrochloride active ingredient in the Aurobindo Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

198. The Aurobindo ANDA refers to and relies upon the Effient® NDA and contains data that, according to Aurobindo Ltd., demonstrates that the Aurobindo Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

199. Aurobindo Ltd. will knowingly accompany the Aurobindo Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Aurobindo Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

200. Aurobindo Ltd. knows that the instructions that will accompany the Aurobindo Products will induce and/or contribute to others using the Aurobindo Products in the manner set forth in the instructions.

201. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Aurobindo Products in

accordance with the instructions provided by Aurobindo Ltd., after the FDA approves the Aurobindo ANDA.

202. Aurobindo Ltd. specifically intends that physicians, health care providers, and/or patients will use the Aurobindo Products in accordance with the instructions provided by Aurobindo Ltd. to directly infringe one or more claims of the '703 and '325 patents. Aurobindo Ltd. therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

203. Aurobindo Ltd. knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Aurobindo Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

204. Aurobindo Ltd. designed the Aurobindo Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Aurobindo Products to use the Aurobindo Products in a way that would infringe the '703 and '325 patents.

205. Aurobindo USA was actively involved in the preparation and/or submission of the Aurobindo ANDA including the Aurobindo Paragraph IV Certification against the '703 and '325 patents.

206. Aurobindo USA actively and knowingly provided Aurobindo Ltd. with material information and support in preparing and submitting the Aurobindo ANDA and has therefore aided and/or abetted in the filing of the Aurobindo ANDA.

207. The Aurobindo Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

208. Unless Aurobindo is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Aurobindo's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

209. Plaintiffs commenced this action within 45 days of receiving the Aurobindo Notification.

COUNT IX: INFRINGEMENT BY AUROBINDO OF U.S. PATENT NO. 8,404,703

210. Aurobindo Ltd.'s filing of the Aurobindo ANDA containing the Aurobindo Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Aurobindo Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

211. Aurobindo USA actively and knowingly aided, abetted, and induced Aurobindo Ltd. to submit the Aurobindo ANDA containing the Aurobindo Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

212. After the FDA approves the Aurobindo ANDA, Aurobindo Ltd. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Aurobindo Products in the United States, import either or both of the Aurobindo

Products into the United States, and/or induce such acts during the term of the '703 patent.

213. Aurobindo Ltd. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Aurobindo ANDA is approved.

214. Aurobindo USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

215. Aurobindo Ltd. lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Aurobindo ANDA and made the Aurobindo Paragraph IV Certification. Accordingly, the Aurobindo Paragraph IV Certification was wholly unjustified.

COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT BY AUROBINDO OF U.S. PATENT NO. 8,404,703

216. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

217. Aurobindo Ltd. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Aurobindo ANDA is approved.

218. Aurobindo USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XI: INFRINGEMENT BY AUROBINDO OF U.S. PATENT NO. 8,569,325

219. Aurobindo Ltd.'s filing of the Aurobindo ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Aurobindo Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

220. Aurobindo USA actively and knowingly aided, abetted, and induced Aurobindo Ltd. to submit the Aurobindo ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

221. If the FDA approves the Aurobindo ANDA, Aurobindo Ltd. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Aurobindo Products in the United States, import either or both of the Aurobindo Products into the United States, and/or induce such acts during the term of the '325 patent.

222. Aurobindo Ltd. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Aurobindo ANDA is approved.

223. Aurobindo USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

224. Aurobindo Ltd. lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Aurobindo ANDA and made the Aurobindo Paragraph IV

Certification. Accordingly, the Aurobindo Paragraph IV Certification was wholly unjustified.

COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT BY AUROBINDO OF U.S. PATENT NO. 8,569,325

225. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

226. Aurobindo Ltd. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Aurobindo ANDA is approved.

227. Aurobindo USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by DRL

228. DRL has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205926 (the "DRL ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "DRL Products") in the United States.

229. The active ingredient and strength of the DRL Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

230. On or about February 7, 2014, DRLI, on behalf of DRL, sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 7, 2014, and an attached memorandum (collectively, the "DRL Notification") stating that DRL had included within its ANDA a

certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the DRL Products in the United States ("DRL Paragraph IV Certification").

231. The prasugrel hydrochloride active ingredient in the DRL Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

232. The DRL ANDA refers to and relies upon the Effient® NDA and contains data that, according to DRL, demonstrates that the DRL Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

233. DRL will knowingly accompany the DRL Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the DRL Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

234. DRL knows that the instructions that will accompany the DRL Products will induce and/or contribute to others using the DRL Products in the manner set forth in the instructions.

235. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the DRL Products in accordance with the instructions provided by DRL, after the FDA approves the DRL ANDA.

236. DRL specifically intends that physicians, health care providers, and/or patients will use the DRL Products in accordance with the instructions provided by DRL

to directly infringe one or more claims of the '703 and '325 patents. DRL therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

237. DRL knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the DRL Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

238. DRL designed the DRL Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the DRL Products to use the DRL Products in a way that would infringe the '703 and '325 patents.

239. The DRL Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

240. Unless DRL is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by DRL's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

241. Plaintiffs commenced this action within 45 days of receiving the DRL Notification.

COUNT XIII: INFRINGEMENT BY DRL OF U.S. PATENT NO. 8,404,703

242. DRL's filing of the DRL ANDA containing the DRL Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the DRL Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

243. After the FDA approves the DRL ANDA, DRL plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the DRL Products in the United States, import either or both of the DRL Products into the United States, and/or induce such acts during the term of the '703 patent.

244. DRL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the DRL ANDA is approved.

245. DRL lacked a good faith basis for alleging invalidity of the '703 patent when it filed the DRL ANDA and made the DRL Paragraph IV Certification. Accordingly, the DRL Paragraph IV Certification was wholly unjustified.

COUNT XIV: DECLARATORY JUDGMENT OF INFRINGEMENT BY DRL OF U.S. PATENT NO. 8,404,703

246. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

247. DRL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the DRL ANDA is approved.

COUNT XV: INFRINGEMENT BY DRL OF U.S. PATENT NO. 8,569,325

248. DRL's filing of the DRL ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the DRL Products in the United States

before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

249. If the FDA approves the DRL ANDA, DRL plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the DRL Products in the United States, import either or both of the DRL Products into the United States, and/or induce such acts during the term of the '325 patent.

250. DRL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the DRL ANDA is approved.

251. DRL lacked a good faith basis for alleging invalidity of the '325 patent when it filed the DRL ANDA and made the DRL Paragraph IV Certification. Accordingly, the DRL Paragraph IV Certification was wholly unjustified.

COUNT XVI: DECLARATORY JUDGMENT OF INFRINGEMENT BY DRL OF U.S. PATENT NO. 8,569,325

252. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

253. DRL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the DRL ANDA is approved.

Infringement by Glenmark

254. GGL has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205922 (the "Glenmark ANDA") to the FDA

pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Glenmark Products") in the United States.

255. The active ingredient and strength of the Glenmark Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

256. On or about January 30, 2014, Glenmark USA sent Lilly and Daiichi Sankyo a letter, dated January 30, 2014, and an attached memorandum (collectively, the "Glenmark Notification") stating that GGL had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Glenmark Products in the United States ("Glenmark Paragraph IV Certification").

257. Glenmark USA, GPL and GGL did not send Ube the Glenmark Notification.

258. The prasugrel hydrochloride active ingredient in the Glenmark Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

259. The Glenmark ANDA refers to and relies upon the Effient® NDA and contains data that, according to GGL, demonstrates that the Glenmark Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

260. GGL will knowingly accompany the Glenmark Products with instructions for use that substantially copy the instructions for Effient® products, including

instructions for administering the Glenmark Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

261. GGL knows that the instructions that will accompany the Glenmark Products will induce and/or contribute to others using the Glenmark Products in the manner set forth in the instructions.

262. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Glenmark Products in accordance with the instructions provided by GGL, after the FDA approves the Glenmark ANDA.

263. GGL specifically intends that physicians, health care providers, and/or patients will use the Glenmark Products in accordance with the instructions provided by GGL to directly infringe one or more claims of the '703 and '325 patents. GGL therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

264. GGL knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Glenmark Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

265. GGL designed the Glenmark Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Glenmark Products to use the Glenmark Products in a way that would infringe the '703 and '325 patents.

266. Glenmark USA and GPL were actively involved in the preparation and/or submission of the Glenmark ANDA including the Glenmark Paragraph IV Certification against the '703 and '325 patents.

267. Glenmark USA and GPL actively and knowingly provided GGL with material information and support in preparing and submitting the Glenmark ANDA and have therefore aided and/or abetted in the filing of the Glenmark ANDA.

268. The Glenmark Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

269. Unless Glenmark is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Glenmark's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

270. Plaintiffs commenced this action within 45 days of receiving the Glenmark Notification.

COUNT XVII: INFRINGEMENT BY GLENMARK OF U.S. PATENT NO. 8,404,703

271. GGL's filing of the Glenmark ANDA containing the Glenmark Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Glenmark Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

272. Glenmark USA and GPL actively and knowingly aided, abetted, and induced GGL to submit the Glenmark ANDA containing the Glenmark Paragraph IV

Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

273. After the FDA approves the Glenmark ANDA, GGL plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Glenmark Products in the United States, import either or both of the Glenmark Products into the United States, and/or induce such acts during the term of the '703 patent.

274. GGL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Glenmark ANDA is approved.

275. Glenmark USA and GPL have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

276. GGL lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Glenmark ANDA and made the Glenmark Paragraph IV Certification. Accordingly, the Glenmark Paragraph IV Certification was wholly unjustified.

COUNT XVIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY GLENMARK OF U.S. PATENT NO. 8,404,703

277. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

278. GGL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Glenmark ANDA is approved.

279. Glenmark USA and GPL have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XIX: INFRINGEMENT BY GLENMARK OF U.S. PATENT NO. 8,569,325

280. GGL's filing of the Glenmark ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Glenmark Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

281. Glenmark USA and GPL actively and knowingly aided, abetted, and induced GGL to submit the Glenmark ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

282. If the FDA approves the Glenmark ANDA, GGL plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Glenmark Products in the United States, import either or both of the Glenmark Products into the United States, and/or induce such acts during the term of the '325 patent.

283. GGL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Glenmark ANDA is approved.

284. Glenmark USA and GPL have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

285. GGL lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Glenmark ANDA and made the Glenmark Paragraph IV Certification. Accordingly, the Glenmark Paragraph IV Certification was wholly unjustified.

COUNT XX: DECLARATORY JUDGMENT OF INFRINGEMENT BY GLENMARK OF U.S. PATENT NO. 8,569,325

286. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

287. GGL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Glenmark ANDA is approved.

288. Glenmark USA and GPL have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Hetero

289. Hetero USA has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205856 (the "Hetero ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Hetero Products") in the United States.

290. The active ingredient and strength of the Hetero Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

291. On or about February 12, 2014, Hetero USA sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 12, 2014, and an attached memorandum (collectively, the "Hetero Notification") stating that Hetero USA had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Hetero Products in the United States ("Hetero Paragraph IV Certification").

292. The prasugrel hydrochloride active ingredient in the Hetero Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

293. The Hetero ANDA refers to and relies upon the Effient® NDA and contains data that, according to Hetero USA, demonstrates that the Hetero Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

294. Hetero USA is aware that the Effient® label states that patients "should also take aspirin (75-mg to 325-mg) daily" while taking Effient®.

295. Hetero USA is aware that patients take Effient® with aspirin and that patients would take the Hetero Products with aspirin.

296. The label of a generic drug, including the package insert which contains prescribing information, must "be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition

filed under 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv).

297. Because the Effient® label instructs that patients "should also take aspirin (75-mg to 325-mg) daily," the label for the Hetero Products will also be required to include such instructions.

298. The label for the Hetero Products will include results from Effient® clinical studies, in particular, the TRITON-TIMI 38 study. In the TRITON-TIMI 38 study, Effient® was administered to patients with aspirin.

299. Hetero USA will knowingly accompany the Hetero Products with instructions for use that substantially copy the instructions for Effient® products, including instructions or suggestions for administering the Hetero Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

300. Hetero USA will actively market the Hetero Products as generic versions of Effient®, which Hetero USA knows contains instructions that patients "should take aspirin (75-mg to 325-mg) daily."

301. Hetero USA knows that the instructions that will accompany the Hetero Products will induce and/or contribute to others using the Hetero Products in the manner set forth in the instructions.

302. Hetero USA knows that marketing the Hetero Products as generic versions of Effient® will induce and/or contribute to others using the Hetero Products in the manner set forth in the Effient® instructions.

303. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Hetero Products in accordance with the instructions provided by Hetero USA, after the FDA approves the Hetero ANDA.

304. Hetero USA specifically intends that physicians, health care providers, and/or patients will use the Hetero Products in accordance with the instructions provided by Hetero USA to directly infringe one or more claims of the '703 and '325 patents. Hetero USA therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

305. Hetero USA knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Hetero Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

306. Hetero USA designed the Hetero Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Hetero Products to use the Hetero Products in a way that would infringe the '703 and '325 patents.

307. Hetero Labs, Hetero V and Hetero Drugs were actively involved in the preparation and/or submission of the Hetero ANDA including the Hetero Paragraph IV Certification against the '703 and '325 patents.

308. Hetero Labs, Hetero V and Hetero Drugs actively and knowingly provided Hetero USA with material information and support in preparing and submitting the Hetero ANDA and have therefore aided and/or abetted in the filing of the Hetero ANDA.

309. The Hetero Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

310. Unless Hetero is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Hetero's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

311. Plaintiffs commenced this action within 45 days of receiving the Hetero Notification.

COUNT XXI: INFRINGEMENT BY HETERO OF U.S. PATENT NO. 8,404,703

312. Hetero USA's filing of the Hetero ANDA containing the Hetero Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Hetero Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

313. Hetero Labs, Hetero V and Hetero Drugs actively and knowingly aided, abetted, and induced Hetero USA to submit the Hetero ANDA containing the Hetero Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

314. After the FDA approves the Hetero ANDA, Hetero USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Hetero Products in the United States, import either or both of the Hetero Products into the United States, and/or induce such acts during the term of the '703 patent.

315. Hetero USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Hetero ANDA is approved.

316. Hetero Labs, Hetero V and Hetero Drugs have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

317. Hetero USA lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Hetero ANDA and made the Hetero Paragraph IV Certification. Accordingly, the Hetero Paragraph IV Certification was wholly unjustified.

COUNT XXII: DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF U.S. PATENT NO. 8,404,703

318. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

319. Hetero USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Hetero ANDA is approved.

320. Hetero Labs, Hetero V and Hetero Drugs have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XXIII: INFRINGEMENT BY HETERO OF U.S. PATENT NO. 8,569,325

321. Hetero USA's filing of the Hetero ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell

and/or sale or inducement thereof of either or both of the Hetero Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

322. Hetero Labs, Hetero V and Hetero Drugs actively and knowingly aided, abetted, and induced Hetero USA to submit the Hetero ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

323. If the FDA approves the Hetero ANDA, Hetero USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Hetero Products in the United States, import either or both of the Hetero Products into the United States, and/or induce such acts during the term of the '325 patent.

324. Hetero USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Hetero ANDA is approved.

325. Hetero Labs, Hetero V and Hetero Drugs have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

326. Hetero USA lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Hetero ANDA and made the Hetero Paragraph IV Certification. Accordingly, the Hetero Paragraph IV Certification was wholly unjustified.

COUNT XXIV: DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF U.S. PATENT NO. 8,569,325

327. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

328. Hetero USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Hetero ANDA is approved.

329. Hetero Labs, Hetero V and Hetero Drugs have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Mylan

330. Mylan Pharms. has knowledge of the '726, '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205927 (the "Mylan ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Mylan Products") in the United States.

331. The active ingredient and strength of the Mylan Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

332. On or about February 7, 2014, Mylan Pharms. sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 7, 2014, and an attached memorandum (collectively, the "Mylan Notification") stating that Mylan Pharms. had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '726, '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use,

importation, sale or offer for sale of the Mylan Products in the United States ("Mylan Paragraph IV Certification").

333. The prasugrel hydrochloride active ingredient in the Mylan Products is the same as the prasugrel hydrochloride active ingredient in Effient® products covered by the '726 patent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5). Mylan Pharms. therefore will directly infringe the '726 patent.

334. The Mylan ANDA refers to and relies upon the Effient® NDA and contains data that, according to Mylan Pharms., demonstrates that the Mylan Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

335. Mylan Pharms. will knowingly accompany the Mylan Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Mylan Products as claimed in the '726 patent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

336. Mylan Pharms. will knowingly accompany the Mylan Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Mylan Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

337. Mylan Pharms. knows that the instructions that will accompany the Mylan Products will induce and/or contribute to others using the Mylan Products in the manner set forth in the instructions.

338. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '726, '703 and '325 patents by using the Mylan Products in accordance with the instructions provided by Mylan Pharms., after the FDA approves the Mylan ANDA.

339. Mylan Pharms. specifically intends that physicians, health care providers, and/or patients will use the Mylan Products in accordance with the instructions provided by Mylan Pharms. to directly infringe one or more claims of the '726, '703 and '325 patents. Mylan Pharms. therefore will actively induce and/or contribute to infringement of the '726, '703 and '325 patents.

340. Mylan Pharms. knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Mylan Products in a manner that directly infringes at least one claim of the '726, '703 and '325 patents.

341. Mylan Pharms. designed the Mylan Products for use in a way that would infringe the '726, '703 and '325 patents and will instruct users of the Mylan Products to use the Mylan Products in a way that would infringe the '726, '703 and '325 patents.

342. Mylan Inc. and Mylan Labs were actively involved in the preparation and/or submission of the Mylan ANDA including the Mylan Paragraph IV Certification against the '726, '703 and '325 patents.

343. Mylan Inc. and Mylan Labs actively and knowingly provided Mylan Pharms. with material information and support in preparing and submitting the Mylan ANDA and has therefore aided and/or abetted in the filing of the Mylan ANDA.

344. The Mylan Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

345. Unless Mylan is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Mylan's infringement of the '726, '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

346. Plaintiffs commenced this action within 45 days of receiving the Mylan Notification.

COUNT XXV: INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 5,288,726

347. The filing by Mylan Pharms. of the Mylan ANDA containing the Mylan Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Mylan Products in the United States before the expiration of the '726 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

348. Mylan Inc. and Mylan Labs actively and knowingly aided, abetted, and induced Mylan Pharms. to submit the Mylan ANDA containing the Mylan Paragraph IV Certification before the expiration of the '726 patent, which is an act of infringement under 35 U.S.C. § 271(b).

349. After the FDA approves the Mylan ANDA, Mylan Pharms. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Mylan Products in the United States, import either or both of the Mylan Products into the United States, and/or induce such acts during the term of the '726 patent.

350. Mylan Pharms. has taken and intends to take active steps to directly infringe the '726 patent under 35 U.S.C. § 271(a), after the Mylan ANDA is approved.

351. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '726 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

352. Mylan Inc. and Mylan Labs have taken and intend to take active steps to directly infringe the '726 patent under 35 U.S.C. § 271(a).

353. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '726 patent under 35 U.S.C. § 271(b) and/or § 271(c).

354. Mylan Pharms. lacked a good faith basis for alleging invalidity of the '726 patent when it filed the Mylan ANDA and made the Mylan Paragraph IV Certification. Accordingly, the Mylan Paragraph IV Certification was wholly unjustified.

COUNT XXVI: DECLARATORY JUDGMENT OF INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 5,288,726

355. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

356. Mylan Pharms. has taken and intends to take active steps to directly infringe the '726 patent under 35 U.S.C. § 271(a), after the Mylan ANDA is approved.

357. Mylan Inc. and Mylan Labs have taken and intend to take active steps to directly infringe the '726 patent under 35 U.S.C. § 271(a), after the Mylan ANDA is approved.

358. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '726 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

359. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '726 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XXVII: INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 8,404,703

360. The filing by Mylan Pharms. of the Mylan ANDA containing the Mylan Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Mylan Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

361. Mylan Inc. and Mylan Labs actively and knowingly aided, abetted, and induced Mylan Pharms. to submit the Mylan ANDA containing the Mylan Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

362. After the FDA approves the Mylan ANDA, Mylan Pharms. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Mylan Products in the United States, import either or both of the Mylan Products into the United States, and/or induce such acts during the term of the '703 patent.

363. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

364. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

365. Mylan Pharms. lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Mylan ANDA and made the Mylan Paragraph IV Certification. Accordingly, the Mylan Paragraph IV Certification was wholly unjustified.

COUNT XXVIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 8,404,703

366. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

367. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

368. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XXIX: INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 8,569,325

369. The filing by Mylan Pharms. of the Mylan ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation,

offer to sell and/or sale or inducement thereof of either or both of the Mylan Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

370. Mylan Inc. and Mylan Labs actively and knowingly aided, abetted, and induced Mylan Pharms. to submit the Mylan ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

371. If the FDA approves the Mylan ANDA, Mylan Pharms. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Mylan Products in the United States, import either or both of the Mylan Products into the United States, and/or induce such acts during the term of the '325 patent.

372. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

373. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

374. Mylan Pharms. lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Mylan ANDA and made the Mylan Paragraph IV Certification. Accordingly, the Mylan Paragraph IV Certification was wholly unjustified.

COUNT XXX: DECLARATORY JUDGMENT OF INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 8,569,325

375. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

376. Mylan Pharms. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

377. Mylan Inc. and Mylan Labs have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Par Pharmaceutical

378. Par has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205700 (the "Par ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Par Products") in the United States.

379. The active ingredient and strength of the Par Product is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

380. On or about December 9, 2013, Par sent Lilly, Daiichi Sankyo, and Ube a letter, dated December 9, 2013, and an attached memorandum (collectively, the "December Par Notification") stating that Par had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use,

importation, sale or offer for sale of the Par Products in the United States ("Paragraph IV Certification").

381. Plaintiffs filed suit against Par Pharmaceutical in this judicial district on January 24, 2014, 2:14-cv-00508-CCC-MF.

382. On or about January 31, 2014, Par sent Lilly, Daiichi Sankyo, and Ube a second letter, dated January 31, 2014, and an attached memorandum (collectively, the "January Par Notification") repeating that Par had included a Paragraph IV Certification within the Par ANDA.

383. Unlike the December Par Notification, the January Par Notification represented that the FDA received the Par ANDA for substantive review.

384. Plaintiffs are therefore filing the instant Complaint against Par Pharmaceutical to preserve its right for a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii) and 21 U.S.C. 355(c)(3)(E)(ii) in response to the January Par Notification.

385. The prasugrel hydrochloride active ingredient in the Par Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

386. The Par ANDA refers to and relies upon the Effient® NDA and contains data that, according to Par, demonstrates that the Par Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

387. Par will knowingly accompany the Par Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for

administering the Par Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

388. Par knows that the instructions that will accompany the Par Products will induce and/or contribute to others using the Par Products in the manner set forth in the instructions.

389. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Par Products in accordance with the instructions provided by Par, after the FDA approves the Par ANDA.

390. Par specifically intends that physicians, health care providers, and/or patients will use the Par Products in accordance with the instructions provided by Par to directly infringe one or more claims of the '703 and '325 patents. Par therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

391. Par knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Par Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

392. Par designed the Par Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Par Products to use the Par Products in a way that would infringe the '703 and '325 patents.

393. Par Pharmaceutical Companies was actively involved in the preparation and/or submission of the Par ANDA including the Paragraph IV Certification against the '703 and '325 patents.

394. Par Pharmaceutical Companies actively and knowingly provided Par with material information and support in preparing and submitting the Par ANDA and has therefore aided and/or abetted in the filing of the Par ANDA.

395. The Par Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

396. Unless Par Pharmaceutical is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Par Pharmaceutical's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

397. Plaintiffs commenced this action within 45 days of the date of the Par January Notification.

COUNT XXXI: INFRINGEMENT BY PAR PHARMACEUTICAL OF U.S. PATENT NO. 8,404,703

398. Par's filing of the Par ANDA containing the Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Par Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

399. Par Pharmaceutical Companies actively and knowingly aided, abetted, and induced Par to submit the Par ANDA containing the Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

400. After the FDA approves the Par ANDA, Par plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Par Products in the United States, import either or both of the Par Products into the United States, and/or induce such acts during the term of the '703 patent.

401. Par has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Par ANDA is approved.

402. Par Pharmaceutical Companies has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

403. Par lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Par ANDA and made the Paragraph IV Certification. Accordingly, the Paragraph IV Certification was wholly unjustified.

COUNT XXXII: DECLARATORY JUDGMENT OF INFRINGEMENT BY PAR PHARMACEUTICAL OF U.S. PATENT NO. 8,404,703

404. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

405. Par has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Par ANDA is approved.

406. Par Pharmaceutical Companies has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XXXIII: INFRINGEMENT BY PAR PHARMACEUTICAL OF U.S. PATENT NO. 8,569,325

407. Par's filing of the Par ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Par Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

408. Par Pharmaceutical Companies actively and knowingly aided, abetted, and induced Par to submit the Par ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

409. If the FDA approves the Par ANDA, Par plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Par Products in the United States, import either or both of the Par Products into the United States, and/or induce such acts during the term of the '325 patent.

410. Par has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Par ANDA is approved.

411. Par Pharmaceutical Companies has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

412. Par lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Par ANDA and made the Paragraph IV Certification. Accordingly, the Paragraph IV Certification was wholly unjustified.

COUNT XXXIV: DECLARATORY JUDGMENT OF INFRINGEMENT BY PAR PHARMACEUTICAL OF U.S. PATENT NO. 8,569,325

413. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

414. Par has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Par ANDA is approved.

415. Par Pharmaceutical Companies has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Sun

416. Sun FZE has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 206012 (the "Sun ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Sun Products") in the United States.

417. The active ingredient and strength of the Sun Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

418. On or about February 13, 2014, Sun FZE sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 13, 2014, and an attached memorandum (collectively, the "Sun Notification") stating that Sun FZE had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sun Products in the United States ("Sun Paragraph IV Certification").

419. The prasugrel hydrochloride active ingredient in the Sun Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

420. The Sun ANDA refers to and relies upon the Effient® NDA and contains data that, according to Sun FZE, demonstrates that the Sun Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

421. Sun FZE will knowingly accompany the Sun Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Sun Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

422. Sun FZE knows that the instructions that will accompany the Sun Products will induce and/or contribute to others using the Sun Products in the manner set forth in the instructions.

423. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Sun Products in accordance with the instructions provided by Sun FZE, after the FDA approves the Sun ANDA.

424. Sun FZE specifically intends that physicians, health care providers, and/or patients will use the Sun Products in accordance with the instructions provided by Sun FZE to directly infringe one or more claims of the '703 and '325 patents. Sun FZE therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

425. Sun FZE knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Sun Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

426. Sun FZE designed the Sun Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Sun Products to use the Sun Products in a way that would infringe the '703 and '325 patents.

427. Sun Pharma, Caraco, and Sun Ltd. were actively involved in the preparation and/or submission of the Sun ANDA including the Sun Paragraph IV Certification against the '703 and '325 patents.

428. Sun Pharma, Caraco, and Sun Ltd. actively and knowingly provided Sun FZE with material information and support in preparing and submitting the Sun ANDA and have therefore aided and/or abetted in the filing of the Sun ANDA.

429. The Sun Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

430. Unless Sun is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Sun's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

431. Plaintiffs commenced this action within 45 days of receiving the Sun Notification.

COUNT XXXV: INFRINGEMENT BY SUN OF U.S. PATENT NO. 8,404,703

432. Sun FZE's filing of the Sun ANDA containing the Sun Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Sun Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

433. Sun Pharma, Caraco, and Sun Ltd. actively and knowingly aided, abetted, and induced Sun FZE to submit the Sun ANDA containing the Sun Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

434. After the FDA approves the Sun ANDA, Sun FZE plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Sun Products in the United States, import either or both of the Sun Products into the United States, and/or induce such acts during the term of the '703 patent.

435. Sun FZE has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sun ANDA is approved.

436. Sun Pharma, Caraco, and Sun Ltd. have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

437. Sun FZE lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Sun ANDA and made the Sun Paragraph IV Certification. Accordingly, the Sun Paragraph IV Certification was wholly unjustified.

COUNT XXXVI: DECLARATORY JUDGMENT OF INFRINGEMENT BY SUN OF U.S.PATENT NO. 8,404,703

438. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

439. Sun FZE has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sun ANDA is approved.

440. Sun Pharma, Caraco, and Sun Ltd. have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XXXVII: INFRINGEMENT BY SUN OF U.S. PATENT NO. 8,569,325

441. Sun FZE's filing of the Sun ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or

sale or inducement thereof of either or both of the Sun Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

442. Sun Pharma, Caraco, and Sun Ltd. actively and knowingly aided, abetted, and induced Sun FZE to submit the Sun ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

443. If the FDA approves the Sun ANDA, Sun FZE plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Sun Products in the United States, import either or both of the Sun Products into the United States, and/or induce such acts during the term of the '325 patent.

444. Sun FZE has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sun ANDA is approved.

445. Sun Pharma, Caraco, and Sun Ltd. have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

446. Sun FZE lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Sun ANDA and made the Sun Paragraph IV Certification. Accordingly, the Sun Paragraph IV Certification was wholly unjustified.

COUNT XXXVIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY SUN OF U.S. PATENT NO. 8,569,325

447. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

448. Sun FZE has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sun ANDA is approved.

449. Sun Pharma, Caraco, and Sun Ltd. have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Teva

450. Teva USA has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205998 (the "Teva ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Teva Products") in the United States.

451. The active ingredient and strength of the Teva Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

452. On or about February 12, 2014, Teva USA sent Lilly, Daiichi Sankyo, and Ube a letter, dated February 12, 2014, and an attached memorandum (collectively, the "Teva Notification") stating that Teva USA had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or

offer for sale of the Teva Products in the United States ("Teva Paragraph IV Certification").

453. The prasugrel hydrochloride active ingredient in the Teva Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

454. The Teva ANDA refers to and relies upon the Effient® NDA and contains data that, according to Teva USA, demonstrates that the Teva Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

455. Teva USA will knowingly accompany the Teva Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Teva Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

456. Teva USA knows that the instructions that will accompany the Teva Products will induce and/or contribute to others using the Teva Products in the manner set forth in the instructions.

457. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Teva Products in accordance with the instructions provided by Teva USA, after the FDA approves the Teva ANDA.

458. Teva USA specifically intends that physicians, health care providers, and/or patients will use the Teva Products in accordance with the instructions provided by Teva USA to directly infringe one or more claims of the '703 and '325 patents. Teva

USA therefore will actively induce and/or contribute to infringement of the ’703 and ’325 patents.

459. Teva USA knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Teva Products in a manner that directly infringes at least one claim of the ’703 and ’325 patents.

460. Teva USA designed the Teva Products for use in a way that would infringe the ’703 and ’325 patents and will instruct users of the Teva Products to use the Teva Products in a way that would infringe the ’703 and ’325 patents.

461. TPIL was actively involved in the preparation and/or submission of the Teva ANDA including the Teva Paragraph IV Certification against the ’703 and ’325 patents.

462. TPIL actively and knowingly provided Teva USA with material information and support in preparing and submitting the Teva ANDA and has therefore aided and/or abetted in the filing of the Teva ANDA.

463. The Teva Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

464. Unless Teva is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Teva’s infringement of the ’703 and ’325 patents. Plaintiffs do not have an adequate remedy at law.

465. Plaintiffs commenced this action within 45 days of receiving the Teva Notification.

COUNT XXXIX: INFRINGEMENT BY TEVA OF U.S. PATENT NO. 8,404,703

466. Teva USA's filing of the Teva ANDA containing the Teva Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Teva Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

467. TPIL actively and knowingly aided, abetted, and induced Teva USA to submit the Teva ANDA containing the Teva Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

468. After the FDA approves the Teva ANDA, Teva USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Teva Products in the United States, import either or both of the Teva Products into the United States, and/or induce such acts during the term of the '703 patent.

469. Teva USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Teva ANDA is approved.

470. TPIL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

471. Teva USA lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Teva ANDA and made the Teva Paragraph IV Certification. Accordingly, the Teva Paragraph IV Certification was wholly unjustified.

COUNT XL: DECLARATORY JUDGMENT OF INFRINGEMENT BY TEVA OF U.S. PATENT NO. 8,404,703

472. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

473. Teva USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Teva ANDA is approved.

474. TPIL has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XLI: INFRINGEMENT BY TEVA OF U.S. PATENT NO. 8,569,325

475. Teva USA's filing of the Teva ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Teva Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

476. TPIL actively and knowingly aided, abetted, and induced Teva USA to submit the Teva ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

477. If the FDA approves the Teva ANDA, Teva USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Teva Products in the United States, import either or both of the Teva Products into the United States, and/or induce such acts during the term of the '325 patent.

478. Teva USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Teva ANDA is approved.

479. TPIL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

480. Teva USA lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Teva ANDA and made the Teva Paragraph IV Certification. Accordingly, the Teva Paragraph IV Certification was wholly unjustified.

COUNT XLII: DECLARATORY JUDGMENT OF INFRINGEMENT BY TEVA OF U.S. PATENT NO. 8,569,325

481. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

482. Teva USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Teva ANDA is approved.

483. TPIL has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Watson

484. Watson Labs has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205785 (the "Watson ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Watson Products") in the United States.

485. The active ingredient and strength of the Watson Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

486. On or about January 27, 2014, Watson Labs sent Lilly, Daiichi Sankyo, and Ube a letter, dated January 27, 2014, and an attached memorandum (collectively, the "Watson Notification") stating that Watson Labs had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Watson Products in the United States ("Watson Paragraph IV Certification").

487. The prasugrel hydrochloride active ingredient in the Watson Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

488. The Watson ANDA refers to and relies upon the Effient® NDA and contains data that, according to Watson Labs, demonstrates that the Watson Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

489. Watson Labs will knowingly accompany the Watson Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Watson Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

490. Watson Labs knows that the instructions that will accompany the Watson Products will induce and/or contribute to others using the Watson Products in the manner set forth in the instructions.

491. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Watson Products in accordance with the instructions provided by Watson Labs, after the FDA approves the Watson ANDA.

492. Watson Labs specifically intends that physicians, health care providers, and/or patients will use the Watson Products in accordance with the instructions provided by Watson Labs to directly infringe one or more claims of the '703 and '325 patents. Watson Labs therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

493. Watson Labs knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Watson Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

494. Watson Labs designed the Watson Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Watson Products to use the Watson Products in a way that would infringe the '703 and '325 patents.

495. Actavis plc, Actavis, and Actavis Pharma were actively involved in the preparation and/or submission of the Watson ANDA including the Watson Paragraph IV Certification against the '703 and '325 patents.

496. Actavis plc, Actavis, and Actavis Pharma actively and knowingly provided Watson Labs with material information and support in preparing and submitting

the Watson ANDA and have therefore aided and/or abetted in the filing of the Watson ANDA.

497. The Watson Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

498. Unless Watson is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

499. Plaintiffs commenced this action within 45 days of receiving the Watson Notification.

COUNT XLIII: INFRINGEMENT BY WATSON OF U.S. PATENT NO. 8,404,703

500. The filing by Watson Labs of the Watson ANDA containing the Watson Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Watson Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

501. Actavis plc, Actavis, and Actavis Pharma actively and knowingly aided, abetted, and induced Watson Labs to submit the Watson ANDA containing the Watson Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

502. After the FDA approves the Watson ANDA, Watson Labs plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both

of the Watson Products in the United States, import either or both of the Watson Products into the United States, and/or induce such acts during the term of the '703 patent.

503. Watson Labs has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Watson ANDA is approved.

504. Actavis plc, Actavis, and Actavis Pharma have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

505. Watson Labs lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Watson ANDA and made the Watson Paragraph IV Certification. Accordingly, the Watson Paragraph IV Certification was wholly unjustified.

COUNT XLIV: DECLARATORY JUDGMENT OF INFRINGEMENT BY WATSON OF U.S. PATENT NO. 8,404,703

506. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

507. Watson Labs has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Watson ANDA is approved.

508. Actavis plc, Actavis, and Actavis Pharma have taken and intend to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XLV: INFRINGEMENT BY WATSON OF U.S. PATENT NO. 8,569,325

509. The filing by Watson Labs of the Watson ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Watson Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

510. Actavis plc, Actavis, and Actavis Pharma actively and knowingly aided, abetted, and induced Watson Labs to submit the Watson ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

511. If the FDA approves the Watson ANDA, Watson Labs plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Watson Products in the United States, import either or both of the Watson Products into the United States, and/or induce such acts during the term of the '325 patent.

512. Watson Labs has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Watson ANDA is approved.

513. Actavis plc, Actavis, and Actavis Pharma have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

514. Watson Labs lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Watson ANDA and made the Watson Paragraph IV Certification. Accordingly, the Watson Paragraph IV Certification was wholly unjustified.

COUNT XLVI: DECLARATORY JUDGMENT OF INFRINGEMENT BY WATSON OF U.S. PATENT NO. 8,569,325

515. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

516. Watson Labs has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Watson ANDA is approved.

517. Actavis plc, Actavis, and Actavis Pharma have taken and intend to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

Infringement by Zydus

518. Zydus USA has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205939 (the "Zydus ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Zydus Products") in the United States.

519. The active ingredient and strength of the Zydus Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

520. On or about February 14, 2014, Zydus USA sent Lilly and Daiichi Sankyo a letter, dated February 14, 2014, and an attached memorandum (collectively, the "Zydus Notification") stating that Zydus USA had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or

offer for sale of the Zydus Products in the United States ("Zydus Paragraph IV Certification").

521. Zydus USA did not send Ube the Zydus Notification.

522. The prasugrel hydrochloride active ingredient in the Zydus Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

523. The Zydus ANDA refers to and relies upon the Effient® NDA and contains data that, according to Zydus USA, demonstrates that the Zydus Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

524. Zydus USA will knowingly accompany the Zydus Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Zydus Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

525. Zydus USA knows that the instructions that will accompany the Zydus Products will induce and/or contribute to others using the Zydus Products in the manner set forth in the instructions.

526. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Zydus Products in accordance with the instructions provided by Zydus USA, after the FDA approves the Zydus ANDA.

527. Zydus USA specifically intends that physicians, health care providers, and/or patients will use the Zydus Products in accordance with the instructions provided by Zydus USA to directly infringe one or more claims of the '703 and '325 patents.

Zydus USA therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

528. Zydus USA knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Zydus Products in a manner that directly infringes at least one claim of the '703 and '325 patents.

529. Zydus USA designed the Zydus Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the Zydus Products to use the Zydus Products in a way that would infringe the '703 and '325 patents.

530. Zydus Cadila was actively involved in the preparation and/or submission of the Zydus ANDA including the Zydus Paragraph IV Certification against the '703 and '325 patents.

531. Zydus Cadila actively and knowingly provided Zydus USA with material information and support in preparing and submitting the Zydus ANDA and has therefore aided and/or abetted in the filing of the Zydus ANDA.

532. The Zydus Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

533. Unless Zydus is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Zydus's infringement of the '703 and '325 patents. Plaintiffs do not have an adequate remedy at law.

534. Plaintiffs commenced this action within 45 days of receiving the Zydus Notification.

COUNT XLVII: INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 8,404,703

535. Zydus USA's filing of the Zydus ANDA containing the Zydus Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Zydus Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

536. Zydus Cadila actively and knowingly aided, abetted, and induced Zydus USA to submit the Zydus ANDA containing the Zydus Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

537. After the FDA approves the Zydus ANDA, Zydus USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Zydus Products in the United States, import either or both of the Zydus Products into the United States, and/or induce such acts during the term of the '703 patent.

538. Zydus USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Zydus ANDA is approved.

539. Zydus Cadila has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

540. Zydus USA lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Zydus ANDA and made the Zydus Paragraph IV Certification. Accordingly, the Zydus Paragraph IV Certification was wholly unjustified.

COUNT XLVIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 8,404,703

541. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

542. Zydus USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Zydus ANDA is approved.

543. Zydus Cadila has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT XLIX: INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 8,569,325

544. Zydus USA's filing of the Zydus ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Zydus Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

545. Zydus Cadila actively and knowingly aided, abetted, and induced Zydus USA to submit the Zydus ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

546. If the FDA approves the Zydus ANDA, Zydus USA plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Zydus Products in the United States, import either or both of the Zydus Products into the United States, and/or induce such acts during the term of the '325 patent.

547. Zydus USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Zydus ANDA is approved.

548. Zydus Cadila has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

549. Zydus USA lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Zydus ANDA and made the Zydus Paragraph IV Certification. Accordingly, the Zydus Paragraph IV Certification was wholly unjustified.

COUNT L: DECLARATORY JUDGMENT OF INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 8,569,325

550. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

551. Zydus USA has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Zydus ANDA is approved.

552. Zydus Cadila has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor against Defendants as follows:

A. That Mylan, either individually or collectively, has infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '726 patent;

B. That Accord, either individually or collectively, has infringed or will infringe, after the Accord ANDA is approved, one or more claims of the '703 patent;

C. That Amneal, either individually or collectively, has infringed or will infringe, after the Amneal ANDA is approved, one or more claims of the '703 patent;

D. That Aurobindo, either individually or collectively, has infringed or will infringe, after the Aurobindo ANDA is approved, one or more claims of the '703 patent;

E. That DRL, either individually or collectively, has infringed or will infringe, after the DRL ANDA is approved, one or more claims of the '703 patent;

F. That Glenmark, either individually or collectively, has infringed or will infringe, after the Glenmark ANDA is approved, one or more claims of the '703 patent;

G. That Hetero, either individually or collectively, has infringed or will infringe, after the Hetero ANDA is approved, one or more claims of the '703 patent;

H. That Mylan, either individually or collectively, has infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '703 patent;

I. That Par Pharmaceutical, either individually or collectively, has infringed or will infringe, after the Par ANDA is approved, one or more claims of the '703 patent;

J. That Sun, either individually or collectively, has infringed or will infringe, after the Sun ANDA is approved, one or more claims of the '703 patent;

K. That Teva, either individually or collectively, has infringed or will infringe, after the Teva ANDA is approved, one or more claims of the '703 patent;

L. That Watson, either individually or collectively, has infringed or will infringe, after the Watson ANDA is approved, one or more claims of the '703 patent;

M. That Zydus, either individually or collectively, has infringed or will infringe, after the Zydus ANDA is approved, one or more claims of the '703 patent;

N. That Accord, either individually or collectively, has infringed or will infringe, after the Accord ANDA is approved, one or more claims of the '325 patent;

O. That Amneal, either individually or collectively, has infringed or will infringe, after the Amneal ANDA is approved, one or more claims of the '325 patent;

P. That Aurobindo, either individually or collectively, has infringed or will infringe, after the Aurobindo ANDA is approved, one or more claims of the '325 patent;

Q. That DRL, either individually or collectively, has infringed or will infringe, after the DRL ANDA is approved, one or more claims of the '325 patent;

R. That Glenmark, either individually or collectively, has infringed or will infringe, after the Glenmark ANDA is approved, one or more claims of the '325 patent;

S. That Hetero, either individually or collectively, has infringed or will infringe, after the Hetero ANDA is approved, one or more claims of the '325 patent;

T. That Mylan, either individually or collectively, has infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '325 patent;

U. That Par Pharmaceutical, either individually or collectively, has infringed or will infringe, after the Par ANDA is approved, one or more claims of the '325 patent;

V. That Sun, either individually or collectively, has infringed or will infringe, after the Sun ANDA is approved, one or more claims of the '325 patent;

W. That Teva, either individually or collectively, has infringed or will infringe, after the Teva ANDA is approved, one or more claims of the '325 patent;

X. That Watson, either individually or collectively, has infringed or will infringe, after the Watson ANDA is approved, one or more claims of the '325 patent;

Y. That Zydus, either individually or collectively, has infringed or will infringe, after the Zydus ANDA is approved, one or more claims of the '325 patent;

Z. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Accord, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Accord Products within the United States, or

importing either or both of the Accord Products into the United States prior to the expiration of the '703 and '325 patents;

AA. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Amneal, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Amneal Products within the United States, or importing either or both of the Amneal Products into the United States prior to the expiration of the '703 and '325 patents;

BB. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Aurobindo, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Aurobindo Products within the United States, or importing either or both of the Aurobindo Products into the United States prior to the expiration of the '703 and '325 patents;

CC. That, pursuant to 35 U.S.C. § 271(e)(4)(B), DRL, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the DRL Products within the United States, or importing either or both of the DRL Products into the United States prior to the expiration of the '703 and '325 patents;

DD. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Glenmark, its officers, agents, servants, and employees, and those persons in active concert or privity

with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Glenmark Products within the United States, or importing either or both of the Glenmark Products into the United States prior to the expiration of the '703 and '325 patents;

EE. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Hetero, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Hetero Products within the United States, or importing either or both of the Hetero Products into the United States prior to the expiration of the '703 and '325 patents;

FF. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Mylan Products within the United States, or importing either or both of the Mylan Products into the United States prior to the expiration of the '726, '703 and '325 patents;

GG. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Par Pharmaceutical, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Par Products within the United States, or importing either or both of the Par Products into the United States prior to the expiration of the '703 and '325 patents;

HH. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Sun, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Sun Products within the United States, or importing either or both of the Sun Products into the United States prior to the expiration of the '703 and '325 patents;

II. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Teva, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Teva Products within the United States, or importing either or both of the Teva Products into the United States prior to the expiration of the '703 and '325 patents;

JJ. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Watson, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Watson Products within the United States, or importing either or both of the Watson Products into the United States prior to the expiration of the '703 and '325 patents;

KK. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Zydus, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Zydus Products within the United States, or

importing either or both of the Zydus Products into the United States prior to the expiration of the '703 and '325 patents;

LL. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Accord ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

MM. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Amneal ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

NN. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

OO. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the DRL ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

PP. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Glenmark ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

QQ. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Hetero ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

RR. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Mylan ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '726, '703 and '325 patents, including any extensions;

SS. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Par ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

TT. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Sun ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

UU. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Teva ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

VV. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Watson ANDA under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

WW. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Zydus ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

XX. If Accord commercially makes, uses, sells or offers to sell either or both of the Accord Products within the United States, or imports either or both of the Accord Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

YY. If Amneal commercially makes, uses, sells or offers to sell either or both of the Amneal Products within the United States, or imports either or both of the Amneal Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

ZZ. If Aurobindo commercially makes, uses, sells or offers to sell either or both of the Aurobindo Products within the United States, or imports either or both of the Aurobindo Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that

Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

AAA. If DRL commercially makes, uses, sells or offers to sell either or both of the DRL Products within the United States, or imports either or both of the DRL Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

BBB. If Glenmark commercially makes, uses, sells or offers to sell either or both of the Glenmark Products within the United States, or imports either or both of the Glenmark Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

CCC. If Hetero commercially makes, uses, sells or offers to sell either or both of the Hetero Products within the United States, or imports either or both of the Hetero Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

DDD. If Mylan commercially makes, uses, sells or offers to sell either or both of the Mylan Products within the United States, or imports either or both of the Mylan Products into the United States, prior to the expiration of any of the '726, '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

EEE. If Par Pharmaceutical commercially makes, uses, sells or offers to sell either or both of the Par Products within the United States, or imports either or both of the Par Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

FFF. If Sun commercially makes, uses, sells or offers to sell either or both of the Sun Products within the United States, or imports either or both of the Sun Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

GGG. If Teva commercially makes, uses, sells or offers to sell either or both of the Teva Products within the United States, or imports either or both of the Teva Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded

monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

HHH. If Watson commercially makes, uses, sells or offers to sell either or both of the Watson Products within the United States, or imports either or both of the Watson Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

III. If Zydus commercially makes, uses, sells or offers to sell either or both of the Zydus Products within the United States, or imports either or both of the Zydus Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

JJJ. That this case be deemed exceptional under 35 U.S.C. § 285;

KKK. A judgment declaring that the '726 patent remains valid and enforceable;

LLL. A judgment declaring that the '703 patent remains valid and enforceable;

MMM. A judgment declaring that the '325 patent remains valid and enforceable;

NNN. That Plaintiffs be awarded reasonable attorney's fees, costs, and expenses;

OOO. That Plaintiffs be awarded such other relief as the Court deems just and proper.

Dated: March 13, 2014

Respectfully submitted,

By: */s/ John Brenner*

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