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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. HEC PHARM GROUP, HEC PHARM CO., LTD., HEC PHARM USA, MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., ZYDUS PHARMACEUTICALS USA, INC., CADILA HEALTHCARE LTD., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., PRINSTON	Civil Action No. 3:15-cv-05982-PGS-TJB

PHARMACEUTICAL INC., SOLCO HEALTHCARE U.S., LLC, HUAHAI US INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., INVAGEN PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD, and ASSIA CHEMICAL INDUSTRIES LTD.	)
Defendants	)

AMENDED COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants HEC Pharm Group; HEC Pharm Co., Ltd.; HEC Pharm USA; Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan Laboratories Limited; Intas Pharmaceuticals Limited; Accord Healthcare, Inc.; Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.; Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.; Zydus Pharmaceuticals USA, Inc.; Cadila Healthcare Ltd.; MSN Laboratories Private Limited; MSN Pharmaceuticals, Inc.; Prinston Pharmaceutical Inc.; Solco Healthcare U.S. LLC; Huahai US Inc.; Zhejiang Huahai Pharmaceutical Co., Ltd.; Invagen Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Ltd.; Sun Pharma Global FZE; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; and, Assia Chemical Industries Ltd. hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' TRADJENTA® (linagliptin) and JENTADUETO® (linagliptin and metformin hydrochloride) tablets prior to the expiration of United States Patent Nos. 7,407,955, 8,119,648, 8,178,541, 8,673,927, 8,846,695, and 8,853,156.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff, Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

5. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

6. BIPI, BII, BIPKG and BIC are collectively referred to hereinafter as "Boehringer Ingelheim."

7. On information and belief, Defendant HEC Pharm Group ("HEC Group") is a company organized and existing under the laws of China, having a principal place of business at Dong Yang Guang Park, Shangsha, Chang'an, Dongguan, Guangdong, 523871, China.

8. On information and belief, HEC Group is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs. On information and belief, HEC Group established Defendants HEC Pharm Co., Ltd. and HEC Pharm USA Inc. for the purpose of manufacturing, distributing, marketing, and selling its generic drug products throughout the United States.

9. On information and belief, Defendant HEC Pharm Co., Ltd. ("HEC Ltd.") is a company organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China. On information and belief, HEC Ltd. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States.

10. On information and belief, based in part on representations on their website at www.hecpharm.com, HEC Group and HEC Ltd. hold themselves out as a unitary entity. On information and belief, HEC Group and HEC Ltd., themselves and through their U.S. agent, Defendant HEC Pharm USA Inc., manufacture and/or distribute generic drugs for sale and use throughout the United States, including in the State of New Jersey.

11. On information and belief, HEC Pharm USA Inc. ("HEC USA") is a company organized and existing under the laws of New Jersey, having a principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

12. On information and belief, HEC USA is the U.S. agent of HEC Group and HEC Ltd., wherein following FDA approval of an ANDA, HEC Ltd. manufactures and supplies the approved generic product to HEC USA, which then markets and sells the product throughout the United States at the direction, under the control, and for the direct benefit of HEC Ltd. and HEC Group.

13. On information and belief, Defendants HEC Ltd. and HEC USA are wholly owned subsidiaries and agents of Defendant HEC Group.

14. On information and belief, the acts of HEC Ltd. complained of herein were done with the cooperation, participation, and assistance of HEC USA and HEC Group.

15. HEC Ltd., HEC Group, and HEC USA are collectively referred to hereinafter as "HEC."

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

17. On information and belief, Mylan Pharms is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

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

19. On information and belief, 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.

20. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Labs, which, in turn is a wholly-owned subsidiary of Mylan Inc.

21. On information and belief, the acts of Mylan Pharms complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

22. Mylan Pharms, Mylan Labs, and Mylan Inc. are collectively referred to herein as "Mylan."

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

24. On information and belief, AHI is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

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

26. On information and belief, AHI is a wholly-owned subsidiary of Intas.

27. On information and belief, the acts of AHI complained of herein were done with the cooperation, participation, and assistance of Intas.

28. Defendants AHI and Intas are collectively referred to herein as "Accord."

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

30. On information and belief, 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.

31. On information and belief, Aurobindo USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

32. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

33. On information and belief, the acts of Aurobindo Ltd. complained of herein were done with the cooperation, participation, and assistance of Aurobindo USA.

34. Aurobindo USA and Aurobindo Ltd. are collectively referred to herein as "Aurobindo."

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

36. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("DRLI") is a corporation organized and existing under the laws of the State of New Jersey, having 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.

37. On information and belief, DRLL is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

38. On information and belief, DRLI is a wholly-owned subsidiary of DRLL.

39. On information and belief, the acts of DRLL complained of herein were done with the cooperation, participation, and assistance of DRLI.

40. DRLI and DRLL are collectively referred to herein as "DRL"

41. On information and belief, Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus USA") is a corporation organized and existing under the laws of the State of New Jersey, having 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.

42. On information and belief, Zydus USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

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

44. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

45. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Cadila.

46. Zydus USA and Zydus Cadila are collectively referred to hereinafter as "Zydus."

47. On information and belief, Defendant MSN Laboratories Private Limited ("MSN Labs") is a corporation organized and existing under the laws of India, having a principal place of business at Sy No-317 &323, Rudraram (Village), Patancheru Mandal, Medak Dist.-502 329, Telangana, India.

48. On information and belief, Defendant MSN Pharmaceuticals, Inc. ("MSN Inc.") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 343 Thornall Street, Suite 678, Edison, NJ 08837.

49. On information and belief, MSN Labs and MSN Inc. are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

50. On information and belief, MSN Inc. is a wholly owned subsidiary of MSN Labs.

51. On information and belief, the acts of MSN Labs complained of herein were done with the cooperation, participation, and assistance of MSN Inc.

52. MSN Inc. and MSN Labs are collectively referred to hereinafter as "MSN."

53. On information and belief, Prinston Pharmaceutical Inc. ("Prinston") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

54. On information and belief, defendant Prinston is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

55. On information and belief, Defendant Solco Healthcare U.S., LLC ("Solco") is a Delaware corporation with a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

56. On information and belief, Solco is in the business of, among other things, preparing, manufacturing, marketing, and distributing pharmaceutical products, including Prinston's pharmaceutical products, throughout the United States, including in the State of New

Jersey. According to Prinston's website (http://www.prinstonpharm.com/Subsidiary.html) (last visited August 3, 2015), defendant Solco is the "U.S. sales and marketing division of Prinston Pharmaceutical Inc.," has "FDA-approved manufacturing capabilities," and brings "generic pharmaceutical products to the U.S. market."

57. On information and belief, Solco is a wholly-owned subsidiary of Prinston.

58. On information and belief, Defendant Huahai US Inc. ("Huahai") is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

59. On information and belief, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai") is the ultimate parent company for each of Prinston, Solco and Huahai, each of which share a common place of business in Cranbury, New Jersey.

60. On information and belief, Huahai is in the business of, among other things, preparing, manufacturing, marketing, and distributing pharmaceutical products including Prinston's pharmaceutical products, throughout the United States, including in the State of New Jersey. According to Huahai's website (http://www.huahaius.com/history.html) (last visited August 3, 2015), Huahai provides API for the Zhejiang Huahai group of companies and markets "generic finished dosage products through the subsidiary company, Prinston Pharmaceutical Inc." Further, Huahai has claimed to have "assisted Prinston Pharmaceutical Inc. to get over 15 ANDAs approved by FDA." *See* http://huahaius.com/history.htm (last visited August 3, 2015).

61. On information and belief, the acts of Prinston complained of herein were done with the cooperation, participation, and assistance of Huahai, Solco, and Zhejiang Huahai.

62. Prinston, Huahai, Solco, and Zhejiang Huahai are collectively referred to hereinafter as "Prinston."

63. On information and belief, Defendant Invagen Pharmaceuticals Inc. ("Invagen") is a corporation organized and existing under the laws of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

64. On information and belief, Invagen is in the business of developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

65. On information and belief, Defendant Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (East), Mumbai 400 059, Maharashtra, India.

66. On information and belief, Defendant Sun Pharma Global FZE ("Sun FZE") is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Suite 4 46, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. Sun FZE, itself and through its agent Caraco Pharmaceutical Laboratories, Ltd., sells various drug products in the United States, including in the State of New Jersey.

67. On information and belief, Sun Pharmaceutical Industries, Inc. ("Sun Inc.") is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. Sun

Pharmaceuticals, Inc. is registered to do business in the State of New Jersey and, on information and belief, sells various drug products in the United States, including in the State of New Jersey

68. On information and belief, Sun FZE and Sun Inc. are wholly owned subsidiaries of Sun Ltd.

69. On information and belief, the acts of Sun FZE complained of herein were done with the cooperation, participation, and assistance of Sun Inc. and Sun Ltd.

70. Sun FZE, Sun Inc., and Sun Ltd. are collectively referred to hereinafter as "Sun."

71. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

72. On information and belief, Teva USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

73. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("TPIL") is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petah Tikva 49131, Israel.

74. On information and belief, Defendant Assia Chemical Industries Ltd. ("Assia") is a corporation organized and existing under the laws of Israel, having its principal place of business at Teva-Tech Neot-Hovav Eco-Industrial Park, Emek Sara, P.O Box 2049, Be'er Sheva 8412316, Israel.

75. On information and belief, Teva USA has two places of business in the State of New Jersey.

76. On information and belief, Teva USA is a wholly-owned subsidiary and agent of Defendant TPIL.

77. On information and belief, Assia is a wholly-owned subsidiary of TPIL.

78. On information and belief, the acts of Teva USA complained of herein were done with the cooperation, participation, and assistance of TPIL and Assia.

79. Teva USA, TPIL, and Assia are collectively referred to herein as "Teva."

JURISDICTION AND VENUE

80. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

81. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

PERSONAL JURISDICTION OVER HEC USA

82. Plaintiffs reallege paragraphs 7-15 and 80-81 as if fully set forth herein.

83. On information and belief, HEC USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

84. This Court has personal jurisdiction over HEC USA because, *inter alia*, HEC USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID #

0101018617; (3) intends to market, sell, and/or distribute HEC's infringing ANDA products to residents of this State; (4) is incorporated and maintains a principal place of business in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

85. Additionally, on information and belief, HEC USA has previously consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, Defendant's Answer and Counterclaims in *Novartis AG et al v. HEC Pharm Co., Ltd. et al*, NJD-2-15-cv-01647.

86. Additionally, on information and belief, HEC USA has availed itself of the legal protections of the State of New Jersey, by, among other things, indicating in the Offer for Confidential Access in the Paragraph IV Certifications accompanying ANDA Nos. 208335 and 208336 that "[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey."

PERSONAL JURISDICTION OVER HEC GROUP

87. Plaintiffs reallege paragraphs 7-15 and 80-86 as if fully set forth herein.

88. On information and belief, HEC Group develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

89. This Court has personal jurisdiction over HEC Group because, *inter alia*, HEC Group, on information and belief: (1) intends to market, sell, or distribute HEC's ANDA Products to residents of this State; (2) controls Defendant HEC USA; (3) makes its generic drug products available in this State through HEC USA, which is incorporated and has a principal

place of business in New Jersey; (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. Additionally, on information and belief, HEC Group has previously consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, Defendant's Answer and Counterclaims in *Novartis AG et al v. HEC Pharm Co., Ltd. et al*, NJD-2-15-cv-01647.

91. Alternatively, to the extent the above facts do not establish personal jurisdiction over HEC Group., this Court may exercise jurisdiction over HEC Group pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) HEC Group would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) on information and belief, HEC Group has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over HEC Group satisfies due process.

PERSONAL JURISDICTION OVER HEC LTD

92. Plaintiffs reallege paragraphs 7-15 and 80-91 as if fully set forth herein.

93. On information and belief, HEC Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

94. This Court has personal jurisdiction over HEC Ltd. because, *inter alia*, HEC Ltd, on information and belief: (1) intends to market, sell, or distribute HEC's ANDA Products to residents of this State; (2) makes its generic drug products available in this State through HEC

USA, which is incorporated and has a principal place of business in New Jersey; (3) maintains a broad distributorship network within this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

95. Additionally, on information and belief, HEC Ltd. has previously consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, Defendant's Answer and Counterclaims in *Novartis AG et al v. HEC Pharm Co., Ltd. et al*, NJD-2-15-cv-01647.

96. Alternatively, to the extent the above facts do not establish personal jurisdiction over HEC Ltd., this Court may exercise jurisdiction over HEC Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) HEC Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) HEC Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over HEC Ltd. satisfies due process.

PERSONAL JURISDICTION OVER MYLAN PHARMS.

97. Plaintiffs reallege paragraphs 16-22 and 80-81 as if fully set forth herein.

98. On information and belief, Mylan Pharms develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

99. This Court has personal jurisdiction over Mylan Pharms because, *inter alia*, Mylan Pharms, on information and belief: (1) has substantial, continuous, and systematic

contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100214277; (3) is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (4) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (5) intentionally markets and provides its generic 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.

100. Additionally, Mylan Pharms has initiated at least two lawsuits in New Jersey in 2014, and, on information and belief, has routinely consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Mylan Inc. and Mylan Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp.*, No. 14-4560 (JAP)(LHG) (D.N.J. July 18, 2014); *Mylan Pharmaceuticals Inc. v. Celgene Corp.*, No. 14-2094 (ES)(MAH) (D.N.J. Apr. 3, 2014); Answer, Defenses, and Counterclaims of Mylan Inc. and Mylan Pharmaceuticals Inc. to Plaintiff's Complaint for Patent Infringement, *Warner Chilcott Company, LLC v. Mylan Inc.*, No. 13-6560 (JAP)(TJB) (D.N.J. May 20, 2014), ECF No. Defendants Mylan Pharmaceuticals Inc.'s and Mylan Inc.'s Answer and Counterclaims, *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals Inc.*, No. 13-4158 (MLC)(LHG) (D.N.J. Aug. 23, 2013), ECF No. 11.

101. Additionally, this Court has previously held that Mylan Pharms is subject to personal jurisdiction in this judicial district. *See Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 3:14-cv-07811-MLC-TJB (D.N.J. July 17, 2017); *Otsuka Pharm Co. Ltd. v. Mylan Inc.*, No. 14-cv-458 2015 WL 1305764 (D.N.J. Mar. 23, 2015).

PERSONAL JURISDICTION OVER MYLAN INC.

102. Plaintiffs reallege paragraphs 16-22, 80-81, and 97-101 as if fully set forth herein.

103. On information and belief, Mylan Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

104. This Court has personal jurisdiction over Mylan Inc. because, *inter alia*, Mylan Inc., on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (2) controls Defendant Mylan Pharm.; (3) is registered to do business in the State of New Jersey under entity ID # 0100971292; (4) is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (5) makes its generic drug products available in this State through Mylan Pharm, which is registered to do business in New Jersey; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

105. Additionally, on information and belief, Mylan Inc. has routinely consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Mylan Inc. and Mylan Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp.*, No. 14-4560 (JAP)(LHG) (D.N.J. July 18, 2014); Answer, Defenses, and Counterclaims of Mylan Inc. and Mylan Pharmaceuticals Inc. to Plaintiff's Complaint for Patent Infringement, *Warner Chilcott Company, LLC v. Mylan Inc.*, No. 13-6560 (JAP)(TJB) (D.N.J. May 20, 2014), ECF No. Defendants Mylan Pharmaceuticals Inc.'s and Mylan Inc.'s Answer and Counterclaims, *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals Inc.*, No. 13-4158 (MLC)(LHG) (D.N.J. Aug. 23, 2013).

106. Additionally, this Court has previously held that Mylan Inc. is subject to personal jurisdiction in this judicial district. *See Otsuka Pharm Co. Ltd. v. Mylan Inc.*, No. 14-cv-458 2015 WL 1305764 (D.N.J. Mar. 23, 2015).

PERSONAL JURISDICTION OVER MYLAN LABS

107. Plaintiffs reallege paragraphs 16-22, 80-81, and 97-106 as if fully set forth herein.

108. On information and belief, Mylan Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

109. This Court has personal jurisdiction over Mylan Labs because, *inter alia*, Mylan Labs, on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (2) controls Defendant Mylan Pharm., which is registered to do business in New Jersey; (3) is registered as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services; (4) makes its generic drug products available in this State through Mylan Pharm, which is registered to do business in New Jersey; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

110. Additionally, on information and belief, Mylan Labs has consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Answer, Defenses, and Counterclaims of Mylan Labs in *Novartis Pharms. Corp. et al. v. Mylan Pharms., Inc. et al.* No. 06-cv-02885-MLC-TJB (D.N.J. July 31, 2006)

PERSONAL JURISDICTION OVER AHI

111. Plaintiffs reallege paragraphs 23-28 and 80-81 as if fully set forth herein.

112. On information and belief, AHI develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

113. This Court has personal jurisdiction over AHI because, *inter alia*, AHI, on information and belief: (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.

114. Additionally, on information and belief, AHI has routinely consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Answer, Defenses, and Counterclaims in *Astrazeneca Pharms. LP et al. v. Accord Healthcare, Inc., et al.*, No. 09-cv-00619-JAP-TJB (D.N.J. Mar. 20, 2009); Answer, Defenses, and Counterclaims in *Hoffman-La Roche Inc. v. Accord Healthcare Inc. et al.*, No. 11-cv-01192-ES-CLW (D.N.J. May 31, 2011).

PERSONAL JURISDICTION OVER INTAS

115. Plaintiffs reallege paragraphs 23-28, 80-81, and 111-114 as if fully set forth herein.

116. On information and belief, Intas develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

117. This Court has personal jurisdiction over Intas because, *inter alia*, Intas, on information and belief: (1) intends to market, sell, or distribute Accord's ANDA products to

residents of this State; (2) controls Defendants Accord USA and AHI.; (3) operates through its wholly owned subsidiary Accord USA; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

118. Additionally, on information and belief, Intas has previously consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Answer, Defenses, and Counterclaims in *Astrazeneca Pharms. LP et al. v. Accord Healthcare, Inc., et al.*, No. 09-cv-00619-JAP-TJB (D.N.J. Mar. 20, 2009); Answer, Defenses, and Counterclaims in *Hoffman-La Roche Inc. v. Accord Healthcare Inc. et al.*, No. 11-cv-01192-ES-CLW (D.N.J. May 31, 2011).

119. Alternatively, to the extent the above facts do not establish personal jurisdiction over Intas, this Court may exercise jurisdiction over Intas pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Intas would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Intas has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Intas satisfies due process.

PERSONAL JURISDICTION OVER AUROBINDO USA

120. Plaintiffs reallege paragraphs 29-34 and 80-81 as if fully set forth herein.

121. On information and belief, Aurobindo USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

122. This court has personal jurisdiction over Aurobindo USA because, *inter alia*, Aurobindo USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100921223; (3) intends to market, sell, and/or distribute Aurobindo's infringing ANDA products to residents of this State; (4) maintains a principal place of business in this State; (5) is registered a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

123. Additionally, on information and belief, Aurobindo USA has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Otsuka Pharmaceutical Co., Ltd. v Aurobindo Pharma Limited et al.*, No. 14-cv-03306-JBS-KMW (D.J.N. Nov. 14, 2014); *The Medicines Co. v. Aurobindo Pharma Limited et al.*, No. 14-cv-02367-PGS-DEA (D.N.J. July 3, 2014).

PERSONAL JURISDICTION OVER AUROBINDO LTD.

124. Plaintiffs reallege paragraphs 29-34, 80-81, and 120-123 as if fully set forth herein.

125. On information and belief, Aurobindo Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

126. This Court has personal jurisdiction over Aurobindo Ltd because, *inter alia*, Aurobindo Ltd., on information and belief: (1) intends to market, sell, or distribute Aurobindo's

ANDA products to residents of this State; (2) controls Defendant Aurobindo USA.; (3) operates through its wholly owned subsidiary Aurobindo USA, which has a personal place of business in New Jersey; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

127. Additionally, on information and belief, Aurobindo Ltd. has previously consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Otsuka Pharmaceutical Co., Ltd. v Aurobindo Pharma Limited et al.*, No. 14-cv-03306-JBS-KMW (D.J.N. Nov. 14, 2014); *The Medicines Co. v. Aurobindo Pharma Limited et al.*, No. 14-cv-02367-PGS-DEA (D.N.J. July 3, 2014).

128. Alternatively, to the extent the above facts do not establish personal jurisdiction over Aurobindo Ltd., this Court may exercise jurisdiction over Aurobindo Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Aurobindo Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Aurobindo Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Ltd. satisfies due process.

PERSONAL JURISDICTION OVER DRLI

129. Plaintiffs reallege paragraphs 35-40 and 80-81 as if fully set forth herein.

130. On information and belief, DRLI develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

131. This Court has personal jurisdiction over DRLI because, *inter alia*, DRLI, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100518911; (3) intends to market, sell, and/or distribute DRL's infringing ANDA products to residents of this State; (4) is incorporated in and maintains a principal place of business in this State; (5) is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

132. Additionally, on information and belief, DRLI has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Smithkline Beecham, et al. v. Dr. Reddy's Lab, et al.*, No. 03-cv-05355-FLW-JBR (D.N.J. Jan. 30, 2004).

PERSONAL JURISDICTION OVER DRLL

133. Plaintiffs reallege paragraphs 35-40, 80-81, and 129-132 as if fully set forth herein.

134. On information and belief, DRLL develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

135. This Court has personal jurisdiction over DRLL because, *inter alia*, DRLL, on information and belief: (1) intends to market, sell, or distribute DRL's ANDA products to residents of this State; (2) controls Defendant DRLI; (3) operates through its wholly owned subsidiary DRLI, which is incorporated and has a personal place of business in New Jersey; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

136. Additionally, on information and belief, DRLL has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Smithkline Beecham, et al. v. Dr. Reddy's Lab, et al.*, No. 03-cv-05355-FLW-JBR (D.N.J. Jan. 30, 2004).

137. Alternatively, to the extent the above facts do not establish personal jurisdiction over DRLL, this Court may exercise jurisdiction over DRLL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) DRLL would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) DRLL has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over DRLL satisfies due process.

PERSONAL JURISDICTION OVER ZYDUS USA

138. Plaintiffs reallege paragraphs 41-46 and 80-81 as if fully set forth herein.

139. On information and belief, Zydus USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

140. This Court has personal jurisdiction over Zydus USA because, *inter alia*, Zydus USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is incorporated and maintains a principal place of business in New Jersey; (3) is registered to do business in the State of New Jersey under entity ID # 0100915422; (4) intends to market, sell, and/or distribute Zydus' infringing ANDA products to residents of this State; (5) is registered as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

141. Additionally, on information and belief, Zydus USA has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendant's Answer and Counterclaims in *Roxane Labs, Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:14-cv-05423-SRC-CLW (D.N.J. Oct. 7, 2014); *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010).

PERSONAL JURISDICTION OVER ZYDUS CADILA

142. Plaintiffs reallege paragraphs 41-46, 80-81, and 138-141 as if fully set forth herein.

143. On information and belief, Zydus Cadila develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

144. This Court has personal jurisdiction over Zydus Cadila because, *inter alia*, Zydus Cadila, on information and belief: (1) intends to market, sell, or distribute Zydus' ANDA products to residents of this State; (2) controls Defendant Zydus USA; (3) operates through its wholly owned subsidiary Zydus USA, which is incorporated and maintains a principal place of business in New Jersey; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

145. Additionally, on information and belief, Zydus Cadila has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendants' Answer and Counterclaims in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010).

146. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zydus Cadila, this Court may exercise jurisdiction over Zydus Cadila pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Zydus Candila would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Cadila has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Cadila satisfies due process.

PERSONAL JURISDICTION OVER MSN LABS

147. Plaintiffs reallege paragraphs 47-52 and 80-81 as if fully set forth herein.

148. On information and belief, MSN Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

149. This Court has personal jurisdiction over MSN Labs because, *inter alia*, MSN Labs, on information and belief: (1) intends to market, sell, or distribute MSN's ANDA products to residents of this State; (2) makes its generic drug products available in 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.

150. Additionally, on information and belief, MSN Labs has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendants' Answer and Counterclaims in *Takeda GmbH et al. v. Citron Pharma LLC et al.*, No. 3:15-cv-3383-FLW-TJB (D.N.J. July 21, 2015).

151. Alternatively, to the extent the above facts do not establish personal jurisdiction over MSN Labs, this Court may exercise jurisdiction over MSN Labs pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) MSN Labs would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) MSN Labs has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

PERSONAL JURISDICTION OVER MSN INC.

152. Plaintiffs reallege paragraphs 47-52, 80-81, and 147-151 as if fully set forth herein.

153. On information and belief, MSN Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

154. This Court has personal jurisdiction over MSN Inc. because, *inter alia*, MSN Inc., on information and belief: (1) intends to market, sell, or distribute MSN's ANDA products to residents of this State; (2) is incorporated and maintains a principal place of business in New Jersey; (3) is registered to do business in New Jersey; (4) makes its generic drug products available in this State; (4) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

PERSONAL JURISDICTION OVER PRINSTON

155. Plaintiffs reallege paragraphs 53-62 and 80-81 as if fully set forth herein.

156. On information and belief, Prinston develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

157. This Court has personal jurisdiction over Prinston because, *inter alia*, Prinston, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) maintains a principal place of business in New Jersey; (3) is registered to do business in the State of New Jersey under entity ID # 0101017010; (4) intends to market, sell, and/or distribute Prinston's infringing ANDA products to residents of this State; (5) is registered as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services; (6) operates through its regulatory agent Solco, which maintains a principal place of business in New Jersey; (7) maintains a broad distributorship network within this State; and (8) enjoys substantial income from sales of its generic pharmaceutical products in this State.

158. Additionally, on information and belief, Prinston has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Prinston Pharmaceutical Inc. v. Noven Therapeutics, LLC*, No. 2:15-cv-05308 (D.N.J.); *Takeda GmbH et al. v. Prinston Pharmaceutical Inc.*, No. 3:15-cv-03380 (D.N.J.); *Noven Therapeutics, LLC v. Prinston Pharmaceutical Inc. et al.*, No. 2:14-cv-07400 (D.N.J.); *Otsuka Pharmaceutical Co. v. Zjejiang Huahai Pharmaceutical Co.*, et al., No. 1:14-CV-05537 (D.N.J.).

PERSONAL JURISDICTION OVER SOLCO

159. Plaintiffs reallege paragraphs 53-62, 80-81, and 155-158 as if fully set forth herein.

160. On information and belief, Solco develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

161. This Court has personal jurisdiction over Solco because, *inter alia*, Solco, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) maintains a principal place of business in New Jersey; (3) is registered to do business in the State of New Jersey under entity ID # 0600384729; (4) intends to market, sell, and/or distribute Prinston's infringing ANDA products to residents of this State; (5) is registered as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

162. Additionally, on information and belief, Solco has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting

counterclaims against plaintiffs in this judicial district. *See, e.g.*, *See, e.g.*, *Noven Therapeutics, LLC v. Prinston Pharmaceutical Inc. et al.*, No. 2:14-cv-07400 (D.N.J.); *Otsuka Pharmaceutical Co. v. Zjejiang Huahai Pharmaceutical Co.*, et al., No. 1:14-CV-05537 (D.N.J.).

PERSONAL JURISDICTION OVER HUAHAI

163. Plaintiffs reallege paragraphs 53-62, 80-81, and 155-162 as if fully set forth herein.

164. On information and belief, Huahai develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

165. This Court has personal jurisdiction over Huahai because, *inter alia*, Huahai, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is incorporated and maintains a principal place of business in New Jersey; (3) is registered to do business in the State of New Jersey under entity ID # 0100931368; (4) intends to market, sell, and/or distribute Prinston's infringing ANDA products to residents of this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

166. Additionally, on information and belief, Huahai has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *See, e.g.*, *Noven Therapeutics, LLC v. Prinston Pharmaceutical Inc. et al.*, No. 2:14-cv-07400 (D.N.J.); *Otsuka Pharmaceutical Co. v. Zjejiang Huahai Pharmaceutical Co.*, et al., No. 1:14-CV-05537 (D.N.J.).

PERSONAL JURISDICTION OVER ZHEJIANG HUAHAI

167. Plaintiffs reallege paragraphs 53-62, 80-81, and 155-166 as if fully set forth herein.

168. On information and belief, Zhejiang Huahai develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

169. This Court has personal jurisdiction over Zhejiang Huahaibecause, *inter alia*, Zhejiang Huahai, on information and belief: (1) intends to market, sell, or distribute Prinston's ANDA products to residents of this State; (2) operates through its wholly owned subsidiaries Prinston, Solco, and Huahai, which are incorporated and/or maintain a principal place of business in New Jersey; (3) makes its generic drug products available in 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.

170. Additionally, on information and belief, Zhejiang Huahai has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g., Otsuka Pharmaceutical Co. v. Zhejiang Huahai Pharmaceutical Co.*, et al., No. 1:14-CV-05537 (D.N.J.).

171. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zhejiang Huahai, this Court may exercise jurisdiction over Zhejiang Huahai pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Zhejiang Huahai would be a foreign defendant not subject to personal jurisdiction in the courts of any

State; and (c) Zhejiang Huahai has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zhejiang Huahai satisfies due process.

PERSONAL JURISDICTION OVER INVAGEN

172. Plaintiffs reallege paragraphs 63-64 and 80-81 as if fully set forth herein.

173. On information and belief, Invagen develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

174. This Court has personal jurisdiction over Invagen because, *inter alia*, Invagen, on information and belief: (1) intends to market, sell, or distribute Invagen's ANDA products to residents of this State; (2) makes its generic drug products available in this State; (2) maintains a broad distributorship network within this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

175. Additionally, on information and belief, Invagen has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendant's Answer, Defenses and Counterclaims in *Shire Development LLC et al. v. Invagen Pharmaceitucals, Inc.*, No. 2:15-cv-367-SRC-CLW (D.N.J. Jan. 6, 2015); *Roxane Labs., Inc. v. Chamber Pharmaceuticals, Inc. et al.*, No. 2:14-cv-04042-SRC-CLW (D.N.J. Aug. 13, 2014).

PERSONAL JURISDICTION OVER SUN FZE

176. Plaintiffs reallege paragraphs 65-70 and 80-81 as if fully set forth herein.

177. On information and belief, Sun FZE develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

178. This Court has personal jurisdiction over Sun FZE because, *inter alia*, Sun FZE, on information and belief: (1) intends to market, sell, or distribute Sun's ANDA 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.

179. Additionally, on information and belief, Sun FZE has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Depomed, Inc. et al. v. Sun Pharma Global FZE, et al.*, No. 3:11-cv-03553-JAP-TJB (D.N.J. July 28, 2011); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, No. 14-cv-6397-JBS-KMW (D.N.J. Dec. 11, 2014).

180. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun FZE, this Court may exercise jurisdiction over Sun FZE pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun FZE would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun FZE has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun FZE satisfies due process.

PERSONAL JURISDICTION OVER SUN INC.

181. Plaintiffs reallege paragraphs 65-70, 80-81, and 176-180 as if fully set forth herein.

182. On information and belief, Sun Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

183. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc., on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in this state under entity ID # 0100970132; (3) is registered as a Wholesale Drug & Medical Device manufacturer and wholesaler by the New Jersey Department of Health and Senior Services; (4) intends to market, sell, and/or distribute Sun's infringing ANDA products to residents of this State; (5) maintains a broad distributorship network within this State; and (6) on information and belief, enjoys substantial income from sales of its generic pharmaceutical products in this State.

184. Additionally, on information and belief, Sun Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Janssen Pharms. Inc. v Sun Pharma Global FZE et al.*, No. 2:11-cv-6089-SRC-CLW (D.N.J. Dec. 27, 2011); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd. et al.*, No. 14-cv-4307-JBS-KMW (D.N.J. Nov. 19, 2014); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, No. 14-cv-6397-JBS-KMW (D.N.J. Dec. 11, 2014).[1]

PERSONAL JURISDICTION OVER SUN LTD.

185. Plaintiffs reallege paragraphs 65-70, 80-81, and 176-184 as if fully set forth herein.

[1] Upon information and belief, Sun Pharmaceuticals Industries, Inc. merged into Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") on or about February 28, 2013, with Caraco as the surviving corporation. The name of the surviving corporation was again changed to Sun Pharmaceutical Industries Inc. on or about July 1, 2014.

186. On information and belief, Sun Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

187. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun Ltd., on information and belief: (1) intends to market, sell, or distribute Sun's ANDA products to residents of this State; (2) controls Defendants Sun FZE, and Sun Inc.; (3) operates through its wholly owned subsidiaries Sun FZE and Sun Inc., at least one of which has a principal place of business in New Jersey, is registered to do business in New Jersey, and is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

188. Additionally, on information and belief, Sun Ltd. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, Defendants' Answer, Defenses, and Counterclaims in *Depomed, Inc. et al. v. Sun Pharma Global FZE, et al.*, No. 3:11-cv-03553-JAP-TJB (D.N.J. July 28, 2011); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, No. 14-cv-6397-JBS-KMW (D.N.J. Dec. 11, 2014).

189. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun Ltd., this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing

and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

PERSONAL JURISDICTION OVER TEVA USA

190. Plaintiffs reallege paragraphs 71-81 as if fully set forth herein.

191. On information and belief, Teva USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

192. This Court has personal jurisdiction over Teva USA because, *inter alia*, Teva USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100250184; (3) intends to market, sell, and/or distribute Teva's infringing ANDA Products to residents of this State; (4) has two places of business in this State; (5) is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

193. Additionally, on information and belief, Teva USA has routinely consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, *Helsinn Healthcare, S.A., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-6341 (MLC)(DEA) (D.N.J. Oct. 13, 2014); *United Therapeutics Corporation v. Teva Pharmaceuticals USA, Inc.*, No. 14-5498 (PGS)(LHG) (D.N.J. Sept. 2, 2014); *Novo Nordisk Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-4248 (MAS)(DEA) (D.N.J. July 3, 2014); *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-3558 (MLC)(TJB) (D.N.J. June 4, 2014); *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd.*, et al., No. 14-5672

(MAS)(TJB) (D.N.J. Sept. 11, 2014); *Teva Pharmaceutical Industries, Ltd., et al. v. Glenmark Generics, Inc. USA, et al.*, No. 08-4355 (GEB)(DEA) (D.N.J. Aug. 29, 2008).

PERSONAL JURISDICTION OVER TPIL

194. Plaintiffs reallege paragraphs 71-81, and 190-193 as if fully set forth herein.

195. On information and belief, TPIL develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

196. This Court has personal jurisdiction over TPIL because, *inter alia*, TPIL, on information and belief: (1) intends to market, sell, or distribute Teva's ANDA Products to residents of this State; (2) controls Defendant Teva USA; (3) makes its generic drug products available in this State through Teva USA, which has two places of business in New Jersey; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

197. Additionally, on information and belief, TPIL has routinely availed itself of the protections afforded by this Court. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672 (MAS)(TJB) (D.N.J. Sept. 11, 2014); *Teva Pharmaceutical Industries, Ltd., et al. v. Glenmark Generics, Inc. USA, et al.*, No. 08-4355(GEB)(DEA) (D.N.J. Aug. 29, 2008).

198. Alternatively, to the extent the above facts do not establish personal jurisdiction over TPIL, this Court may exercise jurisdiction over TPIL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) TPIL would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) TPIL has sufficient contacts

with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over TPIL satisfies due process.

PERSONAL JURISDICTION OVER ASSIA

199. Plaintiffs reallege paragraphs 71-81 and 190-198 as if fully set forth herein.

200. On information and belief, Assia develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

201. This Court has personal jurisdiction over Assia because, inter alia, Assia, on information and belief: (1) intends to manufacture Teva's ANDA Products for sale and distribution to residents of this State; (2) is a wholly owned subsidiary of TPIL; (3) makes its generic drug products available in this State through Teva USA, which has two places of business in New Jersey; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

202. On information and belief, Teva USA, TPIL, and Assia work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

203. Alternatively, to the extent the above facts do not establish personal jurisdiction over Assia, this Court may exercise jurisdiction over Assia pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Assia would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Assia has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling

generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Assia satisfies due process.

BACKGROUND

U.S. Patent No. 7,407,955

204. On August 5, 2008, the U.S. Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 7,407,955 ("the '955 patent") entitled "8-[3-Amino-peperidin-1-yl-]xanthines, The Preparation Thereof And Their Use As Pharmaceutical Compositions" to inventors Frank Himmelsbach, Elke Langkopf, Matthias Eckhardt, Michael Mark, Roland Maier, Ralf R.H. Lotz, and Mohammand Tadayyon. A true and correct copy of the '955 patent is attached as Exhibit 1.

U.S. Patent No. 8,119,648

205. On February 21, 2012, the PTO duly and legally issued United States Patent No. 8,119,648 ("the '648 patent") entitled "8-[3-Amino-peperidin-1-yl-]xanthines, The Preparation Thereof And Their Use As Pharmaceutical Compositions" to inventors Frank Himmelsbach, Elke Langkopf, Matthias Eckhardt, Michael Mark, Roland Maier, and Ralf Lotz. A true and correct copy of the '648 patent is attached as Exhibit 2.

U.S. Patent No. 8,178,541

206. On May 15, 2012, the PTO duly and legally issued United States Patent No. 8,178,541 ("the '541 patent") entitled "8-[3-Amino-peperidin-1-yl-]xanthines, The Preparation Thereof And Their Use As Pharmaceutical Compositions" to inventors Frank Himmelsbach, Elke Langkopf, Matthias Eckhardt, Michael Mark, Roland Maier, Ralf Lotz, and Mohammand Tadayyon. A true and correct copy of the '541 patent is attached as Exhibit 3.

U.S. Patent No. 8,673,927

207. On March 18, 2014, the PTO duly and legally issued United States Patent No. 8,673,927 ("the '927 patent") entitled "Uses of DPP-IV Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '927 patent is attached as Exhibit 4.

U.S. Patent No. 8,846,695

208. On September 30, 2014, the PTO duly and legally issued United States Patent No. 8,846,695 ("the '695 patent") entitled "Treatment For Diabetes In Patients With Inadequate Glycemic Control Despite Metformin Therapy Comprising A DPP-IV Inhibitor" to inventor Klaus Dugi. A true and correct copy of the '695 patent is attached as Exhibit 5.

U.S. Patent No. 8,853,156

209. On October 7, 2014, the PTO duly and legally issued United States Patent No. 8,853,156 ("the '156 patent") entitled "Treatment For Diabetes In Patients Inappropriate For Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Jurgen Woerle. A true and correct copy of the '156 patent is attached at Exhibit 6.

TRADJENTA® AND JENTADUETO®

210. BIPI is the holder of New Drug Application ("NDA") No. 201280 ("the NDA") for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

211. BIPI is the holder of NDA No. 201281 for linagliptin and metformin hydrochloride tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages, which are sold under the trade name JENTADUETO®.

212. TRADJENTA® and JENTADUETO® are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until May 2, 2016.

213. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '955, '648, '541, '927, '695, and '156 patents are listed in the "Orange Book" with respect to TRADJENTA®.

214. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '955, '648, '541, '927, and '695 patents are listed in the Orange Book with respect to JENTADUETO® in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages.

215. The '955, '648, '541, '927, '695, and '156 patents cover the TRADJENTA® product.

216. The '955, '648, '541, '927, and '695 patents cover the JENTADUETO® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I (HEC ONLY) - INFRINGEMENT OF THE '955 PATENT BY HEC

217. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-216 as if fully set forth herein.

218. On information and belief, HEC submitted ANDA Nos. 208335 and 208336 (the "HEC ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "HEC Linagliptin Product") and linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages (the "HEC Combination Products"), respectively. The products subject to HEC's ANDAs are herein referred to as the "HEC ANDA Products."

219. HEC ANDA No. 208335 refers to and relies upon the TRADJENTA® NDA and contains data that, according to HEC, demonstrate the bioequivalence of the HEC Linagliptin Product and TRADJENTA®.

220. HEC ANDA No. 208336 refers to and relies upon the JENTADUETO® NDA and contains data that, according to HEC, demonstrate the bioequivalence of the HEC Combination Product and JENTADUETO®.

221. Plaintiffs received letters from HEC on or about June 27, 2015 and July 1, 2015, stating that HEC had included certifications in the HEC ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '955, '648, '541, '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the HEC ANDA Products (the "HEC Paragraph IV Certifications").

222. HEC has infringed at least one claim of the '955 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the HEC ANDAs, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC ANDA Products prior to the expiration of the '955 patent.

223. HEC has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the HEC ANDA Products in the event that the FDA approves the HEC ANDAs. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '955 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

224. HEC's manufacture, use, offer to sell, or sale of the HEC ANDA Products in the United States or importation of the HEC ANDA Products into the United States during the term

of the '955 patent would further infringe at least one claim of the '955 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

225. On information and belief, HEC's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '955 patent either literally or under the doctrine of equivalents.

226. On information and belief, the use of HEC's ANDA Products constitutes a material part of at least one of the claims of the '955 patent; HEC knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

227. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would contributorily infringe at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

228. On information and belief, HEC had knowledge of the '955 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

229. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would actively induce infringement of at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

230. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '955 patent.

231. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II (HEC ONLY) - INFRINGEMENT OF THE '648 PATENT BY HEC

232. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-231 as if fully set forth herein.

233. HEC has infringed at least one claim of the '648 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the HEC ANDAs, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC ANDA Products prior to the expiration of the '648 patent.

234. HEC has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the HEC ANDA Products in the event that the FDA approves the HEC ANDAs. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '648 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

235. HEC's manufacture, use, offer to sell, or sale of the HEC ANDA Products in the United States or importation of the HEC ANDA Products into the United States during the term of the '648 patent would further infringe at least one claim of the '648 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

236. On information and belief, HEC's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the '648 patent either literally or under the doctrine of equivalents.

237. On information and belief, the use of HEC's ANDA Products constitutes a material part of at least one of the claims of the '648 patent; HEC knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

238. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would contributorily infringe at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

239. On information and belief, HEC had knowledge of the '648 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

240. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would actively induce infringement of at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

241. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '648 patent.

242. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III (HEC ONLY) - INFRINGEMENT OF THE '541 PATENT BY HEC

243. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-242 as if fully set forth herein.

244. HEC has infringed at least one claim of the '541 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the HEC ANDAs, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC ANDA Products prior to the expiration of the '541 patent.

245. HEC has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the HEC ANDA Products in the event that the FDA approves the HEC ANDA. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '541 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

246. HEC's manufacture, use, offer to sell, or sale of the HEC ANDA Products in the United States or importation of the HEC ANDA Products into the United States during the term of the '541 patent would further infringe at least one claim of the '541 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

247. On information and belief, HEC's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '541 patent either literally or under the doctrine of equivalents.

248. On information and belief, the use of HEC's ANDA Products constitutes a material part of at least one of the claims of the '541 patent; HEC knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '541 patent,

either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

249. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would contributorily infringe at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents.

250. On information and belief, HEC had knowledge of the '541 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents.

251. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would actively induce infringement of at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

252. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '541 patent.

253. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT IV (HEC ONLY) - INFRINGEMENT OF THE '927 PATENT BY HEC

254. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-253 as if fully set forth herein.

255. HEC has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the HEC ANDAs, by which HEC

seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC ANDA Products prior to the expiration of the '927 patent.

256. HEC has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the HEC ANDA Products in the event that the FDA approves the HEC ANDAs. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

257. HEC's manufacture, use, offer to sell, or sale of the HEC ANDA Products in the United States or importation of the HEC ANDA Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

258. On information and belief, HEC's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

259. On information and belief, the use of HEC's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; HEC knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

260. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

261. On information and belief, HEC had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

262. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

263. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '927 patent.

264. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT V (HEC ONLY) - INFRINGEMENT OF THE '695 PATENT BY HEC

265. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-264 as if fully set forth herein.

266. HEC has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the HEC ANDAs, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC ANDA Products prior to the expiration of the '695 patent.

267. HEC declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the HEC ANDA Products in the event that the FDA approves the HEC ANDAs. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

268. HEC's manufacture, use, offer to sell, or sale of the HEC ANDA Products in the United States or importation of the HEC ANDA Products into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

269. On information and belief, HEC's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

270. On information and belief, the use of HEC's ANDA Products constitutes a material part of at least one of the claims of the '695 patent; HEC knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

271. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

272. On information and belief, HEC had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

273. On information and belief, the offering to sell, sale, and/or importation of HEC's ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

274. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '695 patent.

275. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT VI (HEC ONLY) - INFRINGEMENT OF THE '156 PATENT BY HEC

276. Plaintiffs reallege paragraphs 1-15, 80-96, and 204-275 as if fully set forth herein.

277. HEC has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted ANDA No. 208335, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC Linagliptin Product prior to the expiration of the '156 patent.

278. HEC has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States the HEC Linagliptin Product in the event that the FDA approves ANDA No. 208335. Accordingly, an actual and immediate controversy exists regarding HEC's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

279. HEC's manufacture, use, offer to sell, or sale of the HEC Linagliptin Product in the United States or importation of the HEC Linagliptin Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

280. On information and belief, HEC's Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

281. On information and belief, the use of HEC's Linagliptin Product constitutes a material part of at least one of the claims of the '156 patent; HEC knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

282. On information and belief, the offering to sell, sale, and/or importation of HEC's Linagliptin Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

283. On information and belief, HEC had knowledge of the '156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

284. On information and belief, the offering to sell, sale, and/or importation of HEC's Linagliptin Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

285. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing the '156 patent.

286. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT VII (AUROBINDO ONLY) - INFRINGEMENT OF THE '156 PATENT BY AUROBINDO

287. Plaintiffs reallege paragraphs 1-6, 29-34, 80-81, 120-128, and 204-216 as if fully set forth herein.

288. On information and belief, Aurobindo submitted ANDA No. 208415 (the "Aurobindo ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage. The product subject to Aurobindo's ANDA is herein referred to as the "Aurobindo ANDA Product."

289. Aurobindo ANDA No. 208415 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Aurobindo, demonstrate the bioequivalence of the Aurobindo ANDA Product and TRADJENTA®.

290. Plaintiffs received a letter from Aurobindo on or about July 1, 2015, stating that Aurobindo had included a certification in the Aurobindo ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '156 patent are either invalid or will

not be infringed by the commercial manufacture, use, or sale of the Aurobindo ANDA Product (the "Aurobindo Paragraph IV Certification").

291. Aurobindo has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Aurobindo ANDA, by which Aurobindo seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Aurobindo ANDA Product prior to the expiration of the '156 patent.

292. Aurobindo has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Aurobindo ANDA Product in the event that the FDA approves the Aurobindo ANDA. Accordingly, an actual and immediate controversy exists regarding Aurobindo's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

293. Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo ANDA Product in the United States or importation of the Aurobindo ANDA Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

294. On information and belief, Aurobindo's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

295. On information and belief, the use of Aurobindo's ANDA Product constitutes a material part of at least one of the claims of the '156 patent; Aurobindo knows that its ANDA

Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

296. On information and belief, the offering to sell, sale, and/or importation of Aurobindo's ANDA Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

297. On information and belief, Aurobindo had knowledge of the '156 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

298. On information and belief, the offering to sell, sale, and/or importation of Aurobindo's ANDA Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

299. Plaintiffs will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '156 patent.

300. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT VIII (ACCORD ONLY) - INFRINGEMENT OF THE '695 PATENT BY ACCORD

301. Plaintiffs reallege paragraphs 1-6, 23-28, 80-81, 111-119, and 204-216 as if fully set forth herein.

302. On information and belief, Accord submitted ANDA No. 208421 (the "Accord ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin and metformin tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages. The product subject to Accord's ANDA is herein referred to as the "Accord ANDA Product."

303. Accord's ANDA No. 208421 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Accord, demonstrate the bioequivalence of the Accord ANDA Product and JENTADUETO®.

304. Plaintiffs received a letter from Accord on or about June 30, 2015, stating that Accord had included a certification in the Accord ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '695 and '927 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Accord ANDA Product (the "Accord Paragraph IV Certification").

305. Accord has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Accord ANDA, by which Accord seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Accord ANDA Product prior to the expiration of the '695 patent.

306. Accord declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Accord ANDA Product in the event that the FDA approves the Accord ANDA. Accordingly, an actual and immediate controversy exists regarding Accord's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

307. Accord's manufacture, use, offer to sell, or sale of the Accord ANDA Products in the United States or importation of the Accord ANDA Product into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

308. On information and belief, Accord's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

309. On information and belief, the use of Accord's ANDA Product constitutes a material part of at least one of the claims of the '695 patent; Accord knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

310. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

311. On information and belief, Accord had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

312. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

313. Plaintiffs will be substantially and irreparably harmed if Accord is not enjoined from infringing the '695 patent.

314. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT IX (ACCORD ONLY) - INFRINGEMENT OF THE '927 PATENT BY ACCORD

315. Plaintiffs reallege paragraphs 1-6, 23-28, 80-81, 111-119, 204-216, and 301-314 as if fully set forth herein.

316. Accord has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Accord ANDA, by which Accord seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Accord ANDA Product prior to the expiration of the '927 patent.

317. Accord has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Accord ANDA Product in the event that the FDA approves the Accord ANDA. Accordingly, an actual and immediate controversy exists regarding Accord's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

318. Accord's manufacture, use, offer to sell, or sale of the Accord ANDA Products in the United States or importation of the Accord ANDA Product into the United States during the

term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

319. On information and belief, Accord's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

320. On information and belief, the use of Accord's ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Accord knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

321. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

322. On information and belief, Accord had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

323. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

324. Plaintiffs will be substantially and irreparably harmed if Accord is not enjoined from infringing the '927 patent.

325. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT X (INVAGEN ONLY) - INFRINGEMENT OF THE '695 PATENT BY INVAGEN

326. Plaintiffs reallege paragraphs 1-6, 63-64, 80-81, 172-175, and 204-216 as if fully set forth herein.

327. On information and belief, Invagen submitted ANDA No. 208423 (the "Invagen ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin tablets, for oral use, in 5 mg dosage. The product subject to the Invagen ANDA is herein referred to as the "Invagen ANDA Product."

328. Invagen's ANDA No. 208423 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Accord, demonstrate the bioequivalence of the Invagen ANDA Product and TRADJENTA®.

329. Plaintiffs received a letter from Invagen on or about June 30, 2015, stating that Invagen had included a certification in the Invagen ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '695 and '927 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Invagen ANDA Product (the "Invagen Paragraph IV Certification").

330. Invagen has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Invagen ANDA, by which Invagen seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Invagen ANDA Product prior to the expiration of the '695 patent.

331. Invagen declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Invagen ANDA Product in the event that the FDA approves the Invagen ANDA. Accordingly, an actual and immediate controversy exists regarding Invagen's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

332. Invagen's manufacture, use, offer to sell, or sale of the Accord ANDA Products in the United States or importation of the Invagen ANDA Product into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

333. On information and belief, Invagen's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

334. On information and belief, the use of Invagen's ANDA Product constitutes a material part of at least one of the claims of the '695 patent; Invagen knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

335. On information and belief, the offering to sell, sale, and/or importation of the Invagen ANDA Product would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

336. On information and belief, Invagen had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

337. On information and belief, the offering to sell, sale, and/or importation of the Invagen ANDA Product would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

338. Plaintiffs will be substantially and irreparably harmed if Invagen is not enjoined from infringing the '695 patent.

339. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XI (INVAGEN ONLY) - INFRINGEMENT OF THE '927 PATENT BY INVAGEN

340. Plaintiffs reallege paragraphs 1-6, 63-64, 80-81, 172-175, 204-216, and 326-339 as if fully set forth herein.

341. Invagen has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Invagen ANDA, by which Invagen

seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Invagen ANDA Product prior to the expiration of the '927 patent.

342. Invagen has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Invagen ANDA Product in the event that the FDA approves the Invagen ANDA. Accordingly, an actual and immediate controversy exists regarding Invagen's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

343. Invagen's manufacture, use, offer to sell, or sale of the Invagen ANDA Product in the United States or importation of the Invagen ANDA Product into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

344. On information and belief, Invagen's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

345. On information and belief, the use of Invagen's ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Invagen knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

346. On information and belief, the offering to sell, sale, and/or importation of the Invagen ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

347. On information and belief, Invagen had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

348. On information and belief, the offering to sell, sale, and/or importation of the Invagen ANDA Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

349. Plaintiffs will be substantially and irreparably harmed if Invagen is not enjoined from infringing the '927 patent.

350. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XII (DRL ONLY) - INFRINGEMENT OF THE '927 PATENT BY DRL

351. Plaintiffs reallege paragraphs 1-6, 35-40, 80-81, 129-137, and 204-216 as if fully set forth herein.

352. On information and belief, DRL submitted ANDA Nos. 208428 and 208427 (the "DRL ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "DRL Linagliptin Product") and linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages, ("the

DRL Combination Products") respectively. The DRL Linagliptin Product and the DRL Combination Products are herein collectively referred to as the "DRL ANDA Products."

353. DRL ANDA No. 208428 refers to and relies upon the TRADJENTA® NDA and contains data that, according to DRL, demonstrate the bioequivalence of the DRL Linagliptin Product and TRADJENTA®.

354. DRL ANDA No. 208427 refers to and relies upon the JENTADUETO® NDA and contains data that, according to DRL, demonstrate the bioequivalence of the DRL Combination Products and JENTADUETO®.

355. Plaintiffs received letters from DRL on or about July 10, 2015 and July 13, 2015, stating that DRL had included certifications in the DRL ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the DRL ANDA Products (the "DRL Paragraph IV Certifications").

356. DRL has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the DRL ANDA No. 208427, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL Combination Products prior to the expiration of the '927 patent.

357. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL Combination Products in the event that the FDA approves DRL ANDA No. 208427. Accordingly, an actual and immediate controversy

exists regarding DRL's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

358. DRL's manufacture, use, offer to sell, or sale of the DRL Combination Products in the United States or importation of the DRL Combination Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

359. On information and belief, the DRL Combination Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

360. On information and belief, the use of DRL's Combination Products constitutes a material part of at least one of the claims of the '927 patent; DRL knows that its Combination Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its Combination Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

361. On information and belief, the offering to sell, sale, and/or importation of the DRL Combination Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

362. On information and belief, DRL had knowledge of the '927 patent and, by its promotional activities and package inserts for its Combination Products, knows or should know

that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

363. On information and belief, the offering to sell, sale, and/or importation of the DRL Combination Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

364. Plaintiffs will be substantially and irreparably harmed if DRL is not enjoined from infringing the '927 patent.

365. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XIII (DRL ONLY) - INFRINGEMENT OF THE '695 PATENT BY DRL

366. Plaintiffs reallege paragraphs 1-6, 35-40, 80-81, 129-137, 204-216, and 351-365 as if fully set forth herein.

367. DRL has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted DRL ANDA No. 208427, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL Combination Products prior to the expiration of the '695 patent.

368. DRL declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL Combination Products in the event that the FDA approves the DRL ANDA No. 208427. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

369. DRL's manufacture, use, offer to sell, or sale of the DRL Combination Products in the United States or importation of the DRL Combination Products into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

370. On information and belief, the DRL Combination Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

371. On information and belief, the use of DRL's Combination Products constitutes a material part of at least one of the claims of the '695 patent; DRL knows that its Combination Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its Combination Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

372. On information and belief, the offering to sell, sale, and/or importation of the DRL Combination Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

373. On information and belief, DRL had knowledge of the '695 patent and, by its promotional activities and package inserts for its Combination Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

374. On information and belief, the offering to sell, sale, and/or importation of the DRL Combination Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

375. Plaintiffs will be substantially and irreparably harmed if DRL is not enjoined from infringing the '695 patent.

376. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XIV (DRL ONLY) - INFRINGEMENT OF THE '156 PATENT BY DRL

377. Plaintiffs reallege paragraphs 1-6, 35-40, 80-81, 129-137, 204-216, and 351-376 as if fully set forth herein.

378. DRL has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted DRL ANDA No. 208428, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL Linagliptin Product prior to the expiration of the '156 patent.

379. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL Linagliptin Product in the event that the FDA approves the DRL ANDA No. 208428. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

380. DRL's manufacture, use, offer to sell, or sale of the DRL Linagliptin Product in the United States or importation of the DRL Linagliptin Product into the United States during the

term of the ‘156 patent would further infringe at least one claim of the ‘156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

381. On information and belief, the DRL Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘156 patent either literally or under the doctrine of equivalents.

382. On information and belief, the use of DRL’s Linagliptin Product constitutes a material part of at least one of the claims of the ‘156 patent; DRL knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

383. On information and belief, the offering to sell, sale, and/or importation of the DRL Linagliptin Product would contributorily infringe at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents.

384. On information and belief, DRL had knowledge of the ‘156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents.

385. On information and belief, the offering to sell, sale, and/or importation of the DRL Linagliptin Product would actively induce infringement of at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents.

386. Plaintiffs will be substantially and irreparably harmed if DRL is not enjoined from infringing the '156 patent.

387. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XV (MYLAN ONLY) - INFRINGEMENT OF THE '927 PATENT BY MYLAN

388. Plaintiffs reallege paragraphs 1-6, 16-22, 80-81, 97-110, and 204-216 as if fully set forth herein.

389. On information and belief, Mylan submitted ANDA Nos. 208431 and 208430 (the "Mylan ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Mylan Linagliptin Product") and linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages ("the Mylan Combination Products"), respectively. The Mylan Linagliptin Product and the Mylan Combination Products are herein collectively referred to as the "Mylan ANDA Products."

390. Mylan ANDA No. 208431 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the Mylan Linagliptin Product and TRADJENTA®.

391. Mylan ANDA No. 208430 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the Mylan Combination Products and JENTADUETO®.

392. Plaintiffs received letters from Mylan on or about July 13, 2015 and July 15, 2015, stating that Mylan had included certifications in the DRL ANDAs, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Mylan ANDA Products (the "Mylan Paragraph IV Certifications").

393. Mylan has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the '927 patent.

394. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

395. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

396. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

397. On information and belief, the use of Mylan's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; Mylan knows that its ANDA

Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

398. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

399. On information and belief, Mylan had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

400. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

401. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '927 patent.

402. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XVI (MYLAN ONLY) - INFRINGEMENT OF THE '695 PATENT BY MYLAN

403. Plaintiffs reallege paragraphs 1-6, 16-22, 80-81, 97-110, 204-216, and 388-402 as if fully set forth herein.

404. Mylan has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the '695 patent.

405. Mylan declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

406. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

407. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

408. On information and belief, the use of Mylan's ANDA Products constitutes a material part of at least one of the claims of the '695 patent; Mylan knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

409. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

410. On information and belief, Mylan had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

411. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

412. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '695 patent.

413. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XVII (MYLAN ONLY) - INFRINGEMENT OF THE '156 PATENT BY MYLAN

414. Plaintiffs reallege paragraphs 1-6, 16-22, 80-81, 97-110, 204-216, and 388-413 as if fully set forth herein.

415. Mylan has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted Mylan ANDA No. 208431, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan Linagliptin Product prior to the expiration of the '156 patent.

416. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan Linagliptin Product in the event that the FDA approves Mylan ANDA No. 208431. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

417. Mylan's manufacture, use, offer to sell, or sale of the Mylan Linagliptin Product in the United States or importation of the Mylan Linagliptin Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

418. On information and belief, the Mylan Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

419. On information and belief, the use of Mylan's Linagliptin Product constitutes a material part of at least one of the claims of the '156 patent; Mylan knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

420. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

421. On information and belief, Mylan had knowledge of the '156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

422. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

423. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '156 patent.

424. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XVIII (ZYDUS ONLY) - INFRINGEMENT OF THE '955 PATENT BY ZYDUS

425. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, and 204-216 as if fully set forth herein.

426. On information and belief, Zydus submitted ANDA Nos. 208448 and 208449 (the "Zydus ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Zydus Linagliptin Product") and linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages (the "Zydus Combination Products"), respectively. The products subject to the Zydus ANDAs are herein collectively referred to as the "Zydus ANDA Products."

427. Zydus ANDA No. 208448 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of the Zydus Linagliptin Product and TRADJENTA®.

428. Zydus ANDA No. 208449 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of the Zydus Combination Products and JENTADUETO®.

429. Plaintiffs received letters from Zydus on or about July 9, 2015, stating that Zydus had included certifications in the Zydus ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '955, '648, '541, '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Zydus ANDA Products (the "Zydus Paragraph IV Certifications").

430. Zydus has infringed at least one claim of the '955 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '955 patent.

431. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '955 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

432. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the '955 patent would further infringe at least one claim of the '955 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

433. On information and belief, the Zydus ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '955 patent either literally or under the doctrine of equivalents.

434. On information and belief, the use of Zydus's ANDA Products constitutes a material part of at least one of the claims of the '955 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

435. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

436. On information and belief, Zydus had knowledge of the '955 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

437. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '955 patent, either literally or under the doctrine of equivalents.

438. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '955 patent.

439. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XIX (ZYDUS ONLY) - INFRINGEMENT OF THE '648 PATENT BY ZYDUS

440. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, 204-216, and 425-439 as if fully set forth herein.

441. Zydus has infringed at least one claim of the '648 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '648 patent.

442. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '648 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

443. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the '648 patent would further infringe at least one claim of the '648 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

444. On information and belief, the Zydus ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '648 patent either literally or under the doctrine of equivalents.

445. On information and belief, the use of Zydus's ANDA Products constitutes a material part of at least one of the claims of the '648 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

446. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

447. On information and belief, Zydus had knowledge of the '648 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

448. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '648 patent, either literally or under the doctrine of equivalents.

449. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '648 patent.

450. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XX (ZYDUS ONLY) - INFRINGEMENT OF THE '541 PATENT BY ZYDUS

451. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, 204-216, and 425-450 as if fully set forth herein.

452. Zydus has infringed at least one claim of the '541 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '541 patent.

453. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '541 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

454. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the '541 patent would further infringe at least one claim of the '541 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

455. On information and belief, the Zydus ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '541 patent either literally or under the doctrine of equivalents.

456. On information and belief, the use of Zydus's ANDA Products constitutes a material part of at least one of the claims of the '541 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

457. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents.

458. On information and belief, Zydus had knowledge of the '541 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents.

459. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '541 patent, either literally or under the doctrine of equivalents.

460. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '541 patent.

461. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXI (ZYDUS ONLY) - INFRINGEMENT OF THE '927 PATENT BY ZYDUS

462. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, 204-216, and 425-461 as if fully set forth herein.

463. Zydus has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '927 patent.

464. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

465. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

466. On information and belief, the Zydus ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

467. On information and belief, the use of Zydus's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

468. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

469. On information and belief, Zydus had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

470. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

471. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '927 patent.

472. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXII (ZYDUS ONLY) - INFRINGEMENT OF THE '695 PATENT BY ZYDUS

473. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, 204-216, and 425-472 as if fully set forth herein.

474. Zydus has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '695 patent.

475. Zydus declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

476. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

477. On information and belief, the Zydus ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

478. On information and belief, the use of Zydus's ANDA Products constitutes a material part of at least one of the claims of the '695 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

479. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

480. On information and belief, Zydus had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

481. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

482. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '695 patent.

483. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXIII (ZYDUS ONLY) - INFRINGEMENT OF THE '156 PATENT BY ZYDUS

484. Plaintiffs reallege paragraphs 1-6, 41-46, 80-81, 138-146, 204-216, and 425-483 as if fully set forth herein.

485. Zydus has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted ANDA No. 208448, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus Linagliptin Product, prior to the expiration of the '156 patent.

486. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus Linagliptin Product, in the event that the FDA approves ANDA No. 208448. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

487. Zydus's manufacture, use, offer to sell, or sale of the Zydus Linagliptin Product in the United States or importation of the Zydus Linagliptin Products into the United States during

the term of the ‘156 patent would further infringe at least one claim of the ‘156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

488. On information and belief, the Zydus Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘156 patent either literally or under the doctrine of equivalents.

489. On information and belief, the use of Zydus’s Linagliptin Product constitutes a material part of at least one of the claims of the ‘156 patent; Zydus knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

490. On information and belief, the offering to sell, sale, and/or importation of the Zydus Linagliptin Product would contributorily infringe at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents.

491. On information and belief, Zydus had knowledge of the ‘156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ‘156 patent, either literally or under the doctrine of equivalents.

492. On information and belief, the offering to sell, sale, and/or importation of the Zydus Linagliptin Product would actively induce infringement of at least one of the claims of the ‘955 patent, either literally or under the doctrine of equivalents.

493. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '156 patent.

494. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXIV (MSN ONLY) - INFRINGEMENT OF THE '927 PATENT BY MSN

495. Plaintiffs reallege paragraphs 1-6, 47-52, 80-81, 147-154, and 204-216 as if fully set forth herein.

496. On information and belief, MSN submitted ANDA Nos. 208457 and 208459 (the "MSN ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "MSN Linagliptin Product") and linagliptin and metformin hydrochloride tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages (the "MSN Combination Products"). The products subject to the MSN ANDAs are herein collectively referred to as the "MSN ANDA Products."

497. MSN ANDA No. 208457 refers to and relies upon the TRADJENTA® NDA and contains data that, according to MSN, demonstrate the bioequivalence of the MSN Linagliptin Product and TRADJENTA®.

498. MSN ANDA No. 208459 refers to and relies upon the JENTADUETO® NDA and contains data that, according to MSN, demonstrates the bioequivalence of the MSN Combination Products to JENTADUETO®.

499. Plaintiffs received letters from MSN on or about July 9, 2015, stating that MSN had included certifications in the MSN ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV),

that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the MSN ANDA Products (the "MSN Paragraph IV Certifications").

500. MSN has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the MSN ANDAs, by which MSN seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the MSN ANDA Products prior to the expiration of the '927 patent.

501. MSN has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the MSN ANDA Products in the event that the FDA approves the MSN ANDAs. Accordingly, an actual and immediate controversy exists regarding MSN's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

502. MSN's manufacture, use, offer to sell, or sale of the MSN ANDA Products in the United States or importation of the MSN ANDA Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

503. On information and belief, the MSN ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

504. On information and belief, the use of MSN's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; MSN knows that its ANDA

Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

505. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

506. On information and belief, MSN had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

507. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

508. Plaintiffs will be substantially and irreparably harmed if MSN is not enjoined from infringing the '927 patent.

509. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXV (MSN ONLY) - INFRINGEMENT OF THE '695 PATENT BY MSN

510. Plaintiffs reallege paragraphs 1-6, 47-52, 80-81, 147-154, 204-216, and 495-509 as if fully set forth herein.

511. MSN has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the MSN ANDAs, by which MSN seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the MSN ANDA Products prior to the expiration of the '695 patent.

512. MSN declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the MSN ANDA Products in the event that the FDA approves the MSN ANDAs. Accordingly, an actual and immediate controversy exists regarding MSN's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

513. MSN's manufacture, use, offer to sell, or sale of the MSN ANDA Products in the United States or importation of the MSN ANDA Products into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

514. On information and belief, the MSN ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

515. On information and belief, the use of MSN's ANDA Products constitutes a material part of at least one of the claims of the '695 patent; MSN knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

516. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

517. On information and belief, MSN had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

518. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

519. Plaintiffs will be substantially and irreparably harmed if MSN is not enjoined from infringing the '695 patent.

520. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXVI (MSN ONLY) - INFRINGEMENT OF THE '156 PATENT BY MSN

521. Plaintiffs reallege paragraphs 1-6, 47-52, 80-81, 147-154, 204-216, and 495-520 as if fully set forth herein.

522. MSN has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted MSN ANDA No. 208457, by which MSN seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the MSN Linagliptin Product prior to the expiration of the '156 patent.

523. MSN has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the MSN Linagliptin Product in the event that the FDA approves MSN ANDA No. 208457. Accordingly, an actual and immediate controversy exists regarding MSN's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

524. MSN's manufacture, use, offer to sell, or sale of the MSN Linagliptin Product in the United States or importation of the MSN Linagliptin Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

525. On information and belief, the MSN Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

526. On information and belief, the use of MSN's Linagliptin Product constitutes a material part of at least one of the claims of the '156 patent; MSN knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

527. On information and belief, the offering to sell, sale, and/or importation of the MSN Linagliptin Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

528. On information and belief, MSN had knowledge of the '156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

529. On information and belief, the offering to sell, sale, and/or importation of the MSN Linagliptin Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

530. Plaintiffs will be substantially and irreparably harmed if MSN is not enjoined from infringing the '156 patent.

531. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXVII (PRINSTON ONLY) - INFRINGEMENT OF THE '927 PATENT BY PRINSTON

532. Plaintiffs reallege paragraphs 1-6, 53-62, 80-81, 155-171, and 204-216 as if fully set forth herein.

533. On information and belief, Prinston submitted ANDA No. 208472 (the "Prinston ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Prinston ANDA Product").

534. Prinston ANDA No. 208472 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Prinston, demonstrate the bioequivalence of the Prinston ANDA Product and TRADJENTA®.

535. Plaintiffs received a letter from Prinston on or about July 20, 2015, stating that Prinston had included a certification in the Prinston ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Prinston ANDA Product (the "Prinston Paragraph IV Certification").

536. Prinston has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Prinston ANDA, by which Prinston seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Prinston ANDA Product prior to the expiration of the '927 patent.

537. Prinston has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Prinston ANDA Product in the event that the FDA approves the Prinston ANDA. Accordingly, an actual and immediate controversy exists regarding Prinston's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

538. Prinston's manufacture, use, offer to sell, or sale of the Prinston ANDA Product in the United States or importation of the Prinston ANDA Product into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

539. On information and belief, the Prinston ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

540. On information and belief, the use of Prinston ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Prinston knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

541. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

542. On information and belief, Prinston had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

543. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

544. Plaintiffs will be substantially and irreparably harmed if Prinston is not enjoined from infringing the '927 patent.

545. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXVIII (PRINSTON ONLY) - INFRINGEMENT OF THE '695 PATENT BY PRINSTON

546. Plaintiffs reallege paragraphs 1-6, 53-62, 80-81, 155-171, 204-216, and 532-545 as if fully set forth herein.

547. Prinston has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Prinston ANDA, by which Prinston seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Prinston ANDA Product prior to the expiration of the '695 patent.

548. Prinston declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Prinston ANDA Product in the event that the FDA approves the Prinston ANDA. Accordingly, an actual and immediate controversy exists regarding Prinston's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

549. Prinston's manufacture, use, offer to sell, or sale of the Prinston ANDA Product in the United States or importation of the Prinston ANDA Product into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

550. On information and belief, the Prinston ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

551. On information and belief, the use of Prinston ANDA Product constitutes a material part of at least one of the claims of the '695 patent; Prinston knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '695

patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

552. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Product would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

553. On information and belief, Prinston had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

554. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

555. Plaintiffs will be substantially and irreparably harmed if Prinston is not enjoined from infringing the '695 patent.

556. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXIX (PRINSTON ONLY) - INFRINGEMENT OF THE '156 PATENT BY PRINSTON

557. Plaintiffs reallege paragraphs 1-6, 53-62, 80-81, 155-171, 204-216, and 532-556 as if fully set forth herein.

558. Prinston has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Prinston ANDA, by which Prinston seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Prinston ANDA Product prior to the expiration of the '156 patent.

559. Prinston has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Prinston ANDA Product in the event that the FDA approves the Prinston ANDA. Accordingly, an actual and immediate controversy exists regarding Prinston's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

560. Prinston's manufacture, use, offer to sell, or sale of the Prinston ANDA Product in the United States or importation of the Prinston ANDA Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

561. On information and belief, the Prinston ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

562. On information and belief, the use of Prinston ANDA Product constitutes a material part of at least one of the claims of the '156 patent; Prinston knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

563. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

564. On information and belief, Prinston had knowledge of the '156 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

565. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

566. Plaintiffs will be substantially and irreparably harmed if Prinston is not enjoined from infringing the '156 patent.

567. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXX (SUN ONLY) - INFRINGEMENT OF THE '927 PATENT BY SUN

568. Plaintiffs reallege paragraphs 1-6, 65-70, 80-81, 176-189, and 204-216, as if fully set forth herein.

569. On information and belief, Sun submitted ANDA Nos. 208455 and 208454 (the "Sun ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Sun Linagliptin Product") and linagliptin and metformin hydrochloride tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5

mg/1000 mg dosages (the "Sun Combination Products"). The products subject to the Sun ANDAs are herein collectively referred to as the "Sun ANDA Products."

570. Sun ANDA No. 208455 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Sun, demonstrate the bioequivalence of the Sun Linagliptin Product and TRADJENTA®.

571. Sun ANDA No. 208454 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Sun, demonstrates the bioequivalence of the Sun Combination Products to JENTADUETO®.

572. Plaintiffs received letters from Sun on or about July 14, 2015, stating that Sun had included certifications in the Sun ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Sun ANDA Products (the "Sun Paragraph IV Certifications").

573. Sun has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sun ANDAs, by which Sun seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sun ANDA Products prior to the expiration of the '927 patent.

574. Sun has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sun ANDA Producst in the event that the FDA approves the Sun ANDAs. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

575. Sun's manufacture, use, offer to sell, or sale of the Sun ANDA Products in the United States or importation of the Sun ANDA Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

576. On information and belief, the Sun ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

577. On information and belief, the use of Sun's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; Sun knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

578. On information and belief, the offering to sell, sale, and/or importation of the Sun ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

579. On information and belief, Sun had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

580. On information and belief, the offering to sell, sale, and/or importation of the Sun ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

581. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '927 patent.

582. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXXI (SUN ONLY) - INFRINGEMENT OF THE '695 PATENT BY SUN

583. Plaintiffs reallege paragraphs 1-6, 65-70, 80-81, 176-189, 204-216, and 568-582 as if fully set forth herein.

584. Sun has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sun ANDAs, by which Sun seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sun ANDA Products prior to the expiration of the '695 patent.

585. Sun declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sun ANDA Products in the event that the FDA approves the Sun ANDAs. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

586. Sun's manufacture, use, offer to sell, or sale of the Sun ANDA Products in the United States or importation of the Sun ANDA Products into the United States during the term of

the ‘695 patent would further infringe at least one claim of the ‘695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

587. On information and belief, the Sun ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘695 patent either literally or under the doctrine of equivalents.

588. On information and belief, the use of Sun’s ANDA Products constitutes a material part of at least one of the claims of the ‘695 patent; Sun knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

589. On information and belief, the offering to sell, sale, and/or importation of the Sun ANDA Products would contributorily infringe at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

590. On information and belief, Sun had knowledge of the ‘695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

591. On information and belief, the offering to sell, sale, and/or importation of the Sun ANDA Products would actively induce infringement of at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

592. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '695 patent.

593. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXXII (SUN ONLY) - INFRINGEMENT OF THE '156 PATENT BY SUN

594. Plaintiffs reallege paragraphs 1-6, 65-70, 80-81, 176-189, 204-216, and 568-593 as if fully set forth herein.

595. Sun has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted Sun ANDA No. 208455, by which Sun seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sun Linagliptin Product prior to the expiration of the '156 patent.

596. Sun has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sun Linagliptin Product in the event that the FDA approves Sun ANDA No. 208455. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

597. Sun's manufacture, use, offer to sell, or sale of the Sun Linagliptin Product in the United States or importation of the Sun Linagliptin Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

598. On information and belief, the Sun Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

599. On information and belief, the use of Sun's Linagliptin Product constitutes a material part of at least one of the claims of the '156 patent; Sun knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

600. On information and belief, the offering to sell, sale, and/or importation of the Sun Linagliptin Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

601. On information and belief, Sun had knowledge of the '156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

602. On information and belief, the offering to sell, sale, and/or importation of the Sun Linagliptin Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

603. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '156 patent.

604. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXXIII (TEVA ONLY) - INFRINGEMENT OF THE '927 PATENT BY TEVA

605. Plaintiffs reallege paragraphs 1-6, 71-81, 190-216 as if fully set forth herein.

606. On information and belief, Teva submitted ANDA No. 208433 (the "Teva ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Teva ANDA Product").

607. The Teva ANDA refers to and relies upon the TRADJENTA® NDA and contains data that, according to Teva, demonstrate the bioequivalence of the Teva Product and TRADJENTA®.

608. Plaintiffs received a letter from Teva on or about July 17, 2015, stating that Teva had included a certification in the Teva ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Teva ANDA Product (the "Teva Paragraph IV Certification").

609. Teva has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Teva ANDA, by which Teva seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Teva ANDA Product prior to the expiration of the '927 patent.

610. Teva has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Teva ANDA Product in the event that the FDA approves the Teva ANDA. Accordingly, an actual and immediate controversy exists regarding Teva's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

611. Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

612. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

613. On information and belief, the use of Teva's ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Teva knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

614. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

615. On information and belief, Teva had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

616. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

617. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '927 patent.

618. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXXIV (TEVA ONLY) - INFRINGEMENT OF THE '695 PATENT BY TEVA

619. Plaintiffs reallege paragraphs 1-6, 71-81, 190-216, and 605-618 as if fully set forth herein.

620. Teva has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Teva ANDA, by which Teva seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Teva ANDA Product prior to the expiration of the '695 patent.

621. Teva declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Teva ANDA Product in the event that the FDA approves the Teva ANDA. Accordingly, an actual and immediate controversy exists regarding Teva's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

622. Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term

of the ‘695 patent would further infringe at least one claim of the ‘695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

623. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘695 patent either literally or under the doctrine of equivalents.

624. On information and belief, the use of Teva’s ANDA Product constitutes a material part of at least one of the claims of the ‘695 patent; Teva knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

625. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

626. On information and belief, Teva had knowledge of the ‘695 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

627. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would actively induce infringement of at least one of the claims of the ‘695 patent, either literally or under the doctrine of equivalents.

628. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '695 patent.

629. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT XXXV (TEVA ONLY) - INFRINGEMENT OF THE '156 PATENT BY TEVA

630. Plaintiffs reallege paragraphs 1-6, 71-81, 190-216, and 605-629 as if fully set forth herein.

631. Teva has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Teva ANDA, by which Teva seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Teva ANDA Product prior to the expiration of the '156 patent.

632. Teva has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Teva ANDA Product in the event that the FDA approves the Teva ANDA. Accordingly, an actual and immediate controversy exists regarding Teva's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

633. Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

634. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

635. On information and belief, the use of Teva's ANDA Product constitutes a material part of at least one of the claims of the '156 patent; Teva knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

636. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

637. On information and belief, Teva had knowledge of the '156 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

638. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

639. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '156 patent.

640. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A Judgment be entered that HEC has infringed at least one claim of the '955, '648, '541, '927, '695, and/or '156 patents by submitting the HEC ANDAs;

b. A Judgment be entered that Aurobindo has infringed at least one claim of the '156 patent by submitting the Aurobindo ANDA;

c. A Judgment be entered that Accord has infringed at least one claim of the '927 and '695 patents by submitting ANDA No. 208421;

d. A Judgment be entered that Invagen has infringed at least one claim of the '927 and '695 patents by submitting the Invagen ANDA;

e. A Judgment be entered that DRL has infringed at least one claim of the '927 and '695 patents by submitting the DRL ANDAs;

f. A Judgment be entered that Mylan has infringed at least one claim of the '927, '695, and '156 patents by submitting the Mylan ANDAs;

g. A Judgment be entered that Zydus has infringed at least one claim of the '955, '648, '541, '927, '695, and '156 patents by submitting the Zydus ANDAs;

h. A Judgment be entered that MSN has infringed at least one claim of the '927, '695, and '156 patents by submitting the MSN ANDAs;

i. A Judgment be entered that Prinston has infringed at least one claim of the '927, '695, and '156 patents by submitting the Prinston ANDA;

j. A Judgment be entered that Sun has infringed at least one claim of the '927, '695, and '156 patents by submitting the Sun ANDAs;

k. A Judgment be entered that Teva has infringed at least one claim of the '927, '695, and '156 patents by submitting the Teva ANDA;

l. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

m. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '955, '648, '541, '927, '695, and '156 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '955, '648, '541, '927, '695, and '156 patents or such other later time as the Court may determine;

n. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs 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 '955, '648, '541, '927, '695, '156 patents, including any extensions;

o. That Boehringer be awarded monetary relief if Defendants commercially use, offer to sell, or sell their respective proposed generic versions of TRADJENTA® and/or JENTADUETO®

or any other product that infringes or induces or contributes to the infringement of the '955, '648, '541, '927, '695, and/or '156 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

p. Costs and expenses in this action; and

q. Such other and further relief as the Court deems just and appropriate.

Dated: August 5, 2015

CONNELL FOLEY LLP

s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: August 5, 2015

CONNELL FOLEY LLP

s/ Liza M. Walsh

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RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: August 5, 2015

CONNELL FOLEY LLP

s/ Liza M. Walsh

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