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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. SUN PHARMACEUTICAL INDUSTRIES LTD, SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., MYLAN INC., MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES LIMITED, Defendants.	Civil Action No. 3:16-cv-01727-PGS-TJB

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 Sun Pharmaceutical Industries, Ltd; Sun Pharma Global FZE; Sun Pharmaceutical Industries, Inc., (collectively, "Sun"), Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Laboratories Limited (collectively, "Mylan") (Sun and Mylan collectively, the "Defendants") 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 No. 9,173,859.

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 Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

6. 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.

7. 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 Sun Pharmaceutical Industries Inc., sells various drug products in the United States, including in the State of New Jersey.

8. 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 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.

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

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

JURISDICTION AND VENUE

17. 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).

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

PERSONAL JURISDICTION OVER SUN FZE

19. Plaintiffs reallege paragraphs 1-10 as if fully set forth herein.

20. 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.

21. 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.

22. 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); *Boehringer Ingelheim et al. v. HEC Pharm Co., Ltd. et al.*, 3:15-cv-05982-PGS-TJB.

23. 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.

24. Plaintiffs reallege paragraphs 1-10 and 19-23 as if fully set forth herein.

25. 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.

26. 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.

27. 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); *Boehringer Ingelheim et al. v. HEC Pharm Co., Ltd. et al.*, 3:15-cv-05982-PGS-TJB.[1]

PERSONAL JURISDICTION OVER SUN LTD.

28. Plaintiffs reallege paragraphs 1-10 and 19-27 as if fully set forth herein.

29. 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.

30. 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.

31. 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-

[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.

cv-6397-JBS-KMW (D.N.J. Dec. 11, 2014); *Boehringer Ingelheim et al. v. HEC Pharm Co., Ltd. et al.*, 3:15-cv-05982-PGS-TJB.

32. 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 MYLAN PHARMS

33. Plaintiffs reallege paragraphs 1-5 and 11-18 as if fully set forth herein.

34. 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.

35. 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.

36. 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. 19; 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.

37. Additionally, this Court has previously held that Mylan Pharms is subject to personal jurisdiction in this judicial district, including in a related case concerning Mylan's conduct complained of herein. *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); *Boehringer Ingelheim Pharmaceitucals, Inc. et al. v. HEC Pharm Co., Ltd. et al.*, No. 3:15-cv-05982-PGS-TJB (D.N.J. Dec. 1, 2015).

PERSONAL JURISDICTION OVER MYLAN INC.

38. Plaintiffs reallege paragraphs 1-5, 11-18 and 33-37 as if fully set forth herein.

39. 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.

40. 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.

41. 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), 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).

42. Additionally, this Court has previously held that Mylan Inc. is subject to personal jurisdiction in this judicial district, including in a related case concerning Mylan's conduct complained of herein. *See Otsuka Pharm Co. Ltd. v. Mylan Inc.*, No. 14-cv-458 2015 WL 1305764 (D.N.J. Mar. 23, 2015); *Boehringer Ingelheim Pharmaceitucals, Inc. et al. v. HEC Pharm Co., Ltd. et al.*, No. 3:15-cv-05982-PGS-TJB (D.N.J. Dec. 1, 2015).

PERSONAL JURISDICTION OVER MYLAN LABS

43. Plaintiffs reallege paragraphs 1-5, 11-18 and 33-42 as if fully set forth herein.

44. 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.

45. 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.

46. 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).

47. Additionally, this Court has previously held in a related case concerning Mylan's conduct complained of herein, that Mylan Labs is subject to personal jurisdiction in this judicial district. *See Boehringer Ingelheim Pharmaceitucals, Inc. et al. v. HEC Pharm Co., Ltd. et al.*, No. 3:15-cv-05982-PGS-TJB (D.N.J. Dec. 1, 2015).

BACKGROUND

U.S. Patent No. 9,173,859

48. On November 3, 2015, the U.S. Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 9,173,859 ("the '859 patent") entitled "Uses of DPP-IV Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '859 patent is attached as Exhibit 1.

TRADJENTA® AND JENTADUETO®

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

50. BIPI is the holder of NDA No. 201281 ("the JENTADUETO® NDA") 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®.

51. 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.

52. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '859 patent is listed in the "Orange Book" with respect to TRADJENTA® and JENTADUETO®.

53. The '859 patent covers the TRADJENTA® and JENTADUETO® products.

COUNT I (SUN ONLY) - INFRINGEMENT OF THE '859 PATENT BY SUN

54. Plaintiffs reallege paragraphs 1-10 and 17-32 and 48-53 as if fully set forth herein.

55. 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."

56. 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®.

57. 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®.

58. Plaintiffs received letters from Sun on or about December 9, 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 '859 patent 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").

59. Sun has infringed at least one claim of the '859 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 '859 patent.

60. 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 Products in the event that the FDA approves the Sun ANDAs. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '859 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

61. 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 '859 patent either literally or under the doctrine of equivalents.

62. On information and belief, the use of Sun's ANDA Products constitutes a material part of at least one of the claims of the '859 patent; Sun knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '859 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.

63. 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 '859 patent, either literally or under the doctrine of equivalents.

64. On information and belief, Sun had knowledge of the '859 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 '859 patent, either literally or under the doctrine of equivalents.

65. 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 '859 patent, either literally or under the doctrine of equivalents.

66. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '859 patent.

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

COUNT II (MYLAN ONLY) - INFRINGEMENT OF THE '859 PATENT BY MYLAN

68. Plaintiffs reallege paragraphs 1-5, 11-18, and 33-53 as if fully set forth herein.

69. On information and belief, Mylan submitted ANDA Nos. 208430 and 208431 (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 hydrochloride tablets, 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"). The products subject to the Mylan ANDAs are herein collectively referred to as the "Mylan ANDA Products."

70. 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®.

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

72. Plaintiffs received letters from Mylan on or about March 31, 2016, stating that Mylan had included certifications in the Mylan ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '859 patent 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").

73. Mylan has infringed at least one claim of the '859 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 '859 patent.

74. 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 '859 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

75. 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 '859 patent either literally or under the doctrine of equivalents.

76. On information and belief, the use of Mylan's ANDA Products constitutes a material part of at least one of the claims of the '859 patent; Mylan knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '859 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.

77. 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 '859 patent, either literally or under the doctrine of equivalents.

78. On information and belief, Mylan had knowledge of the '859 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 '859 patent, either literally or under the doctrine of equivalents.

79. 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 '859 patent, either literally or under the doctrine of equivalents.

80. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '859 patent.

81. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorneys' 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 Sun has infringed at least one claim of the '859 patent by submitting the Sun ANDAs;

b. A Judgment be entered that Mylan has infringed at least one claim of the '859 patent by submitting the Mylan ANDAs;

c. 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;

d. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them 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 '859 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '859 patent or such other later time as the Court may determine;

e. 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 expiration date of the '859 patent, including any extensions;

f. 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 '859 patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

g. Costs and expenses in this action; and

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

Dated: April 1, 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 related to the following matters: *Boehringer Ingelheim Pharmaceuticals Inc., et al. v. HEC Pharm Group, et al.*, Civil Action No. 3:15-cv-05982-PGS-TJB (D.N.J.) (consolidated).

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court or arbitration or administrative proceeding other than the above referenced matters, nor are there any non-parties known to Plaintiffs at this time 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: April 1, 2016

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: April 1, 2016

CONNELL FOLEY LLP

s/ Liza M. Walsh

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