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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. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., PRINSTON PHARMACEUTICAL INC., SOLCO HEALTHCARE U.S., LLC, HUAHAI US INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., INVAGEN PHARMACEUTICALS INC., Defendants.	Civil Action No. _____

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 Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., (collectively, "DRL"); Prinston Pharmaceutical Inc., Solco Healthcare U.S., LLC, Huahai US Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., (collectively, "Prinston"); and Invagen Pharmaceuticals, Inc., (Invagen) (DRL, Prinston, and Invagen 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 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.

7. 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.

8. 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.

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

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

11. 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.

12. 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.

13. 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.

14. 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 February 10, 2016), 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."

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

16. 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.

17. 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 February 10, 2016), 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 February 10, 2016).

18. 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.

19. 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.

20. 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.

21. 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.

JURISDICTION AND VENUE

22. 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).

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

PERSONAL JURISDICTION OVER DRLI

24. Plaintiffs reallege paragraphs 6-10 and 22-23 as if fully set forth herein.

25. 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.

26. 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.

27. 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); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm. Co.*, Ltd. et al., No. 15-5982 (PGS)(TJB) (D.N.J.).

PERSONAL JURISDICTION OVER DRLL

28. Plaintiffs reallege paragraphs 6-10, 22-23, and 24-27 as if fully set forth herein.

29. 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.

30. 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.

31. 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); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm. Co.*, Ltd. et al., No. 15-5982 (PGS)(TJB) (D.N.J.).

32. 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 PRINSTON

33. Plaintiffs reallege paragraphs 11-20 and 22-23 as if fully set forth herein.

34. 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.

35. 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.

36. 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.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm. Co.*, Ltd. et al., No. 15-5982 (PGS)(TJB) (D.N.J.).

PERSONAL JURISDICTION OVER SOLCO

37. Plaintiffs reallege paragraphs 11-20, 22-23, and 33-36 as if fully set forth herein.

38. 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.

39. 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.

40. 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.*, *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

41. Plaintiffs reallege paragraphs 11-20, 22-23, and 33-40 as if fully set forth herein.

42. 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.

43. 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.

44. 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.*, *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

45. Plaintiffs reallege paragraphs 11-20, 22-23, and 33-44 as if fully set forth herein.

46. 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.

47. This Court has personal jurisdiction over Zhejiang Huahai because, *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.

48. 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.).

49. 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

50. Plaintiffs reallege paragraphs 20-23 as if fully set forth herein.

51. 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.

52. 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.

53. 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).

BACKGROUND

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

54. 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®

55. 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®.

56. 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®.

57. 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.

58. 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®.

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

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

60. Plaintiffs reallege paragraphs 6-10, 22-23, and 24-32 as if fully set forth herein.

61. 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 hydrochloride tablets, 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"). The products subject to the DRL ANDAs are herein collectively referred to as the "DRL ANDA Products."

62. 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®.

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

64. Plaintiffs received letters from DRL on or about April 18, 2016, 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 '859 patent 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").

65. DRL 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 DRL ANDAs, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL ANDA Products prior to the expiration of the '859 patent.

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

67. On information and belief, the DRL 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.

68. On information and belief, the use of DRL's ANDA Products constitute a material part of at least one of the claims of the '859 patent; DRL 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.

69. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products would contributorily infringe at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

70. On information and belief, DRL 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.

71. On information and belief, the offering to sell, sale, and/or importation of the DRL 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.

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

73. 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 (PRINSTON ONLY) - INFRINGEMENT OF THE '859 PATENT BY PRINSTON

74. Plaintiffs reallege paragraphs 11-20, 22-23, and 33-49 as if fully set forth herein.

75. 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 Products").

76. 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 Products and TRADJENTA®.

77. Plaintiffs received a letter from Prinston on or about April 18, 2016 stating that Prinston had included certifications in the Prinston ANDA, 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 Prinston ANDA Products (the "Prinston Paragraph IV Certification").

78. Prinston 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 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 Products prior to the expiration of the '859 patent.

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

80. On information and belief, the Prinston 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.

81. On information and belief, the use of Prinston's ANDA Products constitute a material part of at least one of the claims of the '859 patent; Prinston 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.

82. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would contributorily infringe at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

83. On information and belief, Prinston 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.

84. 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 '859 patent, either literally or under the doctrine of equivalents.

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

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

COUNT III (INVAGEN ONLY) - INFRINGEMENT OF THE '859 PATENT BY INVAGEN

87. Plaintiffs reallege paragraphs 20-23 and 50-53 as if fully set forth herein.

88. 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, for oral use, in 5 mg dosage (the "Invagen ANDA Products").

89. Invagen ANDA No. 208423 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Invagen, demonstrate the bioequivalence of the Invagen ANDA Products Product and TRADJENTA®.

90. Plaintiffs received a letter from Invagen on or about December 2, 2015 stating that Invagen had included certifications in the Invagen ANDA, 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 Invagen ANDA Products (the "Invagen Paragraph IV Certification").

91. Invagen 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 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 Products prior to the expiration of the '859 patent.

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

93. On information and belief, the Invagen 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.

94. On information and belief, the use of Invagen's ANDA Products constitute a material part of at least one of the claims of the '859 patent; Invagen 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.

95. On information and belief, the offering to sell, sale, and/or importation of the Invagen ANDA Products would contributorily infringe at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

96. On information and belief, Invagen 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.

97. On information and belief, the offering to sell, sale, and/or importation of the Invagen 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.

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

99. 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 DRL has infringed at least one claim of the '859 patent by submitting the DRL ANDAs;

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

c. A Judgment be entered that Invagen has infringed at least one claim of the '859 patent by submitting the Invagen ANDA;

d. 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;

e. 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;

f. 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;

g. 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;

h. Costs and expenses in this action; and

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

Dated: April 28, 2016

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 matter: *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 28, 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 28, 2016

CONNELL FOLEY LLP

s/ Liza M. Walsh

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