IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,	)	
Plaintiffs,	)	
v.	)	C.A. No.
GRANULES INDIA LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Granules India Limited ("Granules"), 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' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' JENTADUETO® (linagliptin/metformin hydrochloride) tablets prior to the expiration of United States Patent Nos. 9,155,705; 9,415,016; 10,022,379; 10,973,827; and 11,911,388.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the state of Delaware, having its 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 its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

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

5. BIPI, BII, and BIPKG are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Granules India Limited ("Granules") is a corporation organized and existing under the laws of India, having its principal place of business at My Home Hub, 2nd Floor, 3rd Block, Madhapur Hyderabad 500081 Telangana, India.

7. Granules India Limited is referred to hereinafter as "Granules" or "Defendant."

8. On information and belief, Granules is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware, through its own actions and through the actions of their agents and subsidiaries, including Granules USA, from which Granules derives a substantial portion of its revenue.

9. On information and belief, Granules prepared and submitted ANDA No. 219778 (the "Granules ANDA") for Granules' linagliptin and metformin hydrochloride tablets in 2.5/500 mg, 2.5/850 mg, and 2.5/1000 mg strengths, respectively (the "Granules ANDA Product").

10. On information and belief, Granules intends to commercially manufacture, market, offer for sale, and sell the Granules ANDA Product throughout the United States, including in the state of Delaware, in the event the FDA approves the Granules ANDA.

JURISDICTION AND VENUE

11. 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).

12. Venue is proper in this Court because, among other things, Granules is an Indian corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER GRANULES

13. Plaintiffs reallege paragraphs 1–12 as if fully set forth herein.

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

15. This Court has personal jurisdiction over Granules because, *inter alia*, Granules, on information and belief: (1) has substantial, continuous, and systematic contacts with this state either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the infringing Granules ANDA Product to residents of this state upon approval of ANDA No. 219778, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this state on its own and through at least one of its wholly-owned subsidiaries or agents.

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

THE PATENTS-IN-SUIT

17. On October 13, 2015, the United States Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 9,155,705 ("the '705 patent") entitled "DPP-IV Inhibitor Combined With A Further Antidiabetic Agent, Tablets Comprising Such Formulations, Their Use And Process For Their Preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '705 patent is attached as Exhibit 1. Boehringer is the owner of all right, title, and interest to the '705 patent, including the right to sue for infringement.

18. On August 16, 2016, the PTO duly and legally issued United States Patent No. 9,415,016 ("the '016 patent") entitled "DPP-IV Inhibitor Combined With A Further Antidiabetic Agent, Tablets Comprising Such Formulations, Their Use And Process For Their Preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '016 patent is attached as Exhibit 2. Boehringer is the owner of all right, title, and interest to the '016 patent, including the right to sue for infringement.

19. On July 17, 2018, the PTO duly and legally issued United States Patent No. 10,022,379 ("the '379 patent") entitled "DPP-IV Inhibitor Combined With A Further Antidiabetic Agent, Tablets Comprising Such Formulations, Their Use And Process For Their Preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '379 patent is attached as Exhibit 3. Boehringer is the owner of all right, title, and interest to the '379 patent, including the right to sue for infringement.

20. On April 13, 2021, the PTO duly and legally issued United States Patent No. 10,973,827 ("the '827 patent") entitled "DPP-IV Inhibitor Combined With A Further Antidiabetic Agent, Tablets Comprising Such Formulations, Their Use And Process For Their Preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '827 patent is attached as Exhibit 4. Boehringer is the owner of all right, title, and interest to the '827 patent, including the right to sue for infringement.

21. On February 27, 2024, the PTO duly and legally issued United States Patent No. 11,911,388 ("the '388 patent") entitled "Treatment For Diabetes In Patients With Insufficient Glycemic Control Despite Therapy With An Oral Or Non-Oral Antidiabetic Drug" to inventors Eva Ulrike Graefe-Mody, Thomas Klein, Michael Mark, and Hans-Juergen Woerle. A true and correct copy of the '388 patent is attached as Exhibit 5. Boehringer is the owner of all right, title, and interest to the '388 patent, including the right to sue for infringement.

JENTADUETO®

22. Boehringer is the owner of the approved New Drug Application No. 201281 ("the NDA") for linagliptin and metformin hydrochloride, for oral use, in 2.5/500 mg, 2.5/850 mg, and 2.5/1000 mg dosages, respectively, which is sold under the trade name JENTADUETO®.

23. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '705, '016, '379, '827, and '388 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to JENTADUETO®.

24. The '705, '016, '379, '827, and '388 patents cover the JENTADUETO® product and/or the use thereof.

ACTS GIVING RISE TO THIS ACTION

25. On information and belief, Granules submitted the Granules ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Granules ANDA Product.

26. The Granules ANDA refers to and relies upon the JENTADUETO® NDA and contains data that, according to Granules, demonstrate the bioequivalence of the Granules ANDA Product and JENTADUETO®.

27. Plaintiffs received a letter from Granules dated August 15, 2024 (the "Granules Letter"), stating that Granules had included a certification in the Granules ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '705, '016, '379, '827, and '388 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Granules ANDA Product (the "Granules Paragraph IV Certification"). Therefore, Granules intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Granules ANDA Product prior to the expiration of the '705, '016, '379, '827, and '388 patents.

28. On information and belief, Granules does not dispute that the Granules ANDA Product will infringe the claims of the '388 patents in the Granules Letter.

29. On information and belief, Granules does not assert that the '705, '016, '379, or '827 patents are invalid.

30. Provided here as a representative claim for exemplary purposes, claim 1 of the '705 patent recites: "1. A solid pharmaceutical composition comprising or made from: (a) 1-[(4-methyl-

quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage range from about 0.5 mg to about 10 mg, (b) metformin hydrochloride, (c) a pharmaceutical excipient, and (d) about 1 mg to 50 mg of L-arginine."

31. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '016 patent recites: "1. A pharmaceutical composition comprising or made from: (a) 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage of 2.5 mg or 5 mg, (b) metformin hydrochloride, (c) one or more pharmaceutical excipients, and (d) a basic amino acid having an intramolecular amino group and alkaline characteristics, which basic amino acid is present in an amount sufficient to suppress degradation of said l-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidinl-yl)-xanthine, wherein the pharmaceutical composition is a tablet comprising a film-coat; and wherein the pharmaceutical composition comprises the following amounts (% by weight of total coated tablet mass): 0.1-0.5% of l-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, and 47-85% of metformin hydrochloride."

32. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '379 patent recites: "1. A method of treating type 2 diabetes mellitus comprising orally administering to a patient in need thereof a pharmaceutical composition comprising: (a) 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage of 2.5 mg or 5 mg, (b) metformin hydrochloride, (c) one or more pharmaceutical excipients, and (d) a basic amino acid having an intramolecular amino group and alkaline characteristics, which basic amino acid is present in an amount sufficient to suppress degradation of said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-

amino-piperidin-1-yl)-xanthine, wherein the pharmaceutical composition is a tablet comprising a film-coat; and wherein the pharmaceutical composition comprises the following amounts: 0.1-0.5% of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, 47-85% of metformin hydrochloride, and 0.07-2.2% of the basic amino acid, wherein each of the foregoing percentage amounts are based on the weight of total coated tablet mass."

33. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '827 patent recites: "1. A pharmaceutical composition comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage of 2.5 mg or 5 mg, metformin hydrochloride, and a basic amino acid having an intramolecular amino group and alkaline characteristics in an amount sufficient to suppress degradation of said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, wherein the pharmaceutical composition is in the form of a tablet comprising a film-coat, which film-coated tablet comprises the following amounts (% by weight of total coated tablet mass): 0.1-0.5% of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R) amino-piperidin-1-yl)-xanthine, 47-85% of metformin HCl, 0.07-2.2% of L-arginine as the basic amino acid, 3.9-8.1% of a binder, 2.3-5.9% of a first filler, 0-4.4% of a second filler, 0-33% of a third filler, 0.7-1.5% of a lubricant, and 0.1-0.5% of a glidant."

34. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '388 patent recites: "1. A method for treating metabolic diseases in type 2 diabetes patients with renal impairment and with insufficient glycemic control despite either metformin monotherapy or therapy with metformin in combination with an insulin or an insulin analogue, the method comprising administering a DPP-4 inhibitor which is 1-[(4-methyl-quinazolin-2-

yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, in an oral daily amount of 5 mg, wherein said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, is used in combination with either metformin monotherapy or metformin in combination with an insulin or an insulin analogue."

35. The Granules Paragraph IV Certification offered confidential access to unspecified portions of the Granules ANDA ("Offer of Confidential Access" or "OCA") on terms and conditions set by Granules. Granules requested that Boehringer accept the terms of the OCA before receiving access to the unspecified portions of the Granules ANDA.

36. Since receiving the Granules Paragraph IV Certification, Boehringer has attempted to negotiate with Granules to obtain a copy of the Granules ANDA. These negotiations were unsuccessful. Granules did not agree to Boehringer's proposal or provide a compromise proposal in response, but instead refused to allow modification of the OCA.

37. Granules has refused to provide access to the Granules ANDA under reasonable terms.

COUNT I — INFRINGEMENT OF THE '705 PATENT

38. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–37.

39. Granules has infringed at least one claim of the '705 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Granules ANDA, by which Granules seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Granules ANDA Product prior to the expiration of the '705 patent.

40. Granules has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Granules ANDA Product in the event that the

FDA approves the Granules ANDA. Accordingly, an actual and immediate controversy exists regarding Granules' infringement of the '705 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

41. Granules' manufacture, use, offer to sell, or sale of the Granules ANDA Product in the United States or importation of the Granules ANDA Product into the United States during the term of the '705 patent would further infringe at least one claim of the '705 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

42. On information and belief, the Granules 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 '705 patent either literally or under the doctrine of equivalents.

43. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '705 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '705 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.

44. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States would contributorily infringe at least one of the claims of the '705 patent, either literally or under the doctrine of equivalents.

45. On information and belief, Granules had knowledge of the '705 patent and, by at least its package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '705 patent, either literally or under the doctrine of equivalents.

46. On information and belief, Granules does not assert that the claims of the '705 patent are invalid and in the Granules Paragraph IV Certification, Granules did not assert that the claims of the '705 patent are invalid.

47. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States by Granules would actively induce infringement of at least one of the claims of the '705 patent, either literally or under the doctrine of equivalents.

48. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '705 patent.

COUNT II — INFRINGEMENT OF THE '016 PATENT

49. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–48.

50. Granules has infringed at least one claim of the '016 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Granules ANDA, by which Granules seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Granules ANDA Product prior to the expiration of the '016 patent.

51. Granules has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Granules ANDA Product in the event that the FDA approves the Granules ANDA. Accordingly, an actual and immediate controversy exists regarding Granules' infringement of the '016 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. Granules' manufacture, use, offer to sell, or sale of the Granules ANDA Product in the United States or importation of the Granules ANDA Product into the United States during the term of the '016 patent would further infringe at least one claim of the '016 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

53. On information and belief, the Granules 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 '016 patent either literally or under the doctrine of equivalents.

54. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '016 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '016 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.

55. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States would contributorily infringe at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Granules had knowledge of the '016 patent and, by at least its package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

57. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States by Granules would actively induce infringement of at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

58. On information and belief, Granules does not assert that the claims of the '016 patent are invalid and in the Granules Paragraph IV Certification, Granules did not assert that the claims of the '016 patent are invalid.

59. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '016 patent.

COUNT III — INFRINGEMENT OF THE '379 PATENT

60. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–59.

61. Granules has infringed at least one claim of the '379 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Granules ANDA, by which Granules seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Granules ANDA Product prior to the expiration of the '379 patent.

62. Granules has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Granules ANDA Product in the event that the FDA approves the Granules ANDA. Accordingly, an actual and immediate controversy exists regarding Granules' infringement of the '379 patent under 35 U.S.C. §§ 271 (b) and/or (c).

63. Granules' manufacture, use, offer to sell, or sale of the Granules ANDA Product in the United States or importation of the Granules ANDA Product into the United States during the term of the '379 patent would further infringe at least one claim of the '379 patent under 35 U.S.C. §§ 271 (b) and/or (c).

64. On information and belief, the Granules 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 '379 patent either literally or under the doctrine of equivalents.

65. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '379 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '379 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.

66. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States would contributorily infringe at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

67. On information and belief, Granules had knowledge of the '379 patent and, by at least its package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

68. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States by Granules would actively induce infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

69. On information and belief, Granules does not assert that the claims of the '379 patent are invalid and in the Granules Paragraph IV Certification, Granules did not assert that the claims of the '379 patent are invalid.

70. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '379 patent.

COUNT IV — INFRINGEMENT OF THE '827 PATENT

71. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–70.

72. Granules has infringed at least one claim of the '827 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Granules ANDA, by which Granules seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Granules ANDA Product prior to the expiration of the '827 patent.

73. Granules has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Granules ANDA Product in the event that the FDA approves the Granules ANDA. Accordingly, an actual and immediate controversy exists regarding Granules' infringement of the '827 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

74. Granules' manufacture, use, offer to sell, or sale of the Granules ANDA Product in the United States or importation of the Granules ANDA Product into the United States during the term of the '827 patent would further infringe at least one claim of the '827 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

75. On information and belief, the Granules 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 '827 patent either literally or under the doctrine of equivalents.

76. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '827 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '827 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.

77. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States would contributorily infringe at least one of the claims of the '827 patent, either literally or under the doctrine of equivalents.

78. On information and belief, Granules had knowledge of the '827 patent and, by at least its package inserts for its ANDA Product, knows or should know that they will aid and abet

another's direct infringement of at least one of the claims of the '827 patent, either literally or under the doctrine of equivalents.

79. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States by Granules would actively induce infringement of at least one of the claims of the '827 patent, either literally or under the doctrine of equivalents.

80. On information and belief, Granules does not assert that the claims of the '827 patent are invalid and in the Granules Paragraph IV Certification, Granules did not assert that the claims of the '827 patent are invalid.

81. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '827 patent.

COUNT V — INFRINGEMENT OF THE '388 PATENT

82. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–81.

83. Granules has infringed at least one claim of the '388 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Granules ANDA, by which Granules seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Granules ANDA Product prior to the expiration of the '388 patent.

84. Granules has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Granules ANDA Product in the event that the FDA approves the Granules ANDA. Accordingly, an actual and immediate controversy exists regarding Granules' infringement of the '388 patent under 35 U.S.C. §§ 271 (b) and/or (c).

85. Granules' manufacture, use, offer to sell, or sale of the Granules ANDA Product in the United States or importation of the Granules ANDA Product into the United States during the

term of the ’388 patent would further infringe at least one claim of the ’388 patent under 35 U.S.C. §§ 271 (b) and/or (c).

86. On information and belief, the Granules 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 ’388 patent either literally or under the doctrine of equivalents.

87. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the ’388 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ’388 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.

88. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States would contributorily infringe at least one of the claims of the ’388 patent, either literally or under the doctrine of equivalents.

89. On information and belief, Granules had knowledge of the ’388 patent and, by at least its package inserts for its ANDA Product, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’388 patent, either literally or under the doctrine of equivalents.

90. On information and belief, the offering to sell, sale, and/or importation of the Granules ANDA Product into the United States by Granules would actively induce infringement of at least one of the claims of the ’388 patent, either literally or under the doctrine of equivalents.

91. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '388 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '388 patent.

92. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '388 patent.

PRAYER FOR RELIEF

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

a. A judgment that Granules has infringed at least one claim of the '705, '016, '379, '827, and '388 patents;

b. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 enjoining Granules, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling the Granules ANDA Product within the United States, or importing the Granules ANDA Product into the United States prior to the expiration of the '705, '016, '379, '827, and '388 patents, and (ii) seeking, obtaining or maintaining approval of the Granules ANDA until the expiration of the '705, '016, '379, '827, and '388 patents or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 219778 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 '705, '016, '379, '827, and '388 patents, including any extensions;

d. If Granules manufactures, uses, offers to sell, or sells the Granules ANDA Product within the United States, or imports the Granules ANDA Product into the United States, prior to

the expiration of any of the '705, '016, '379, '827, or '388 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

e. A judgment that this is an exceptional case and that Plaintiffs be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

f. Costs and expenses in this action; and

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

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