IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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 Granules India Limited and Granules Pharmaceuticals, Inc. (collectively, "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' JARDIANCE® (empagliflozin) tablets prior to the expiration of United States Patent Nos. 9,949,998, 10,258,637, 11,090,323, and 11,833,166.

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

5. 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.

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

7. On information and belief, Granules India Limited 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.

8. On information and belief, Granules Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 3701 Concorde Parkway, Chantilly, Virginia, 20151.

9. Granules India Limited and Granules Pharmaceuticals, Inc. are referred to hereinafter as "Granules" or "Defendants."

10. 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.

11. On information and belief, Granules prepared and submitted ANDA No. 220408 (the "Granules ANDA") for Granules' 10 and 25 mg empagliflozin tablets (the "Granules ANDA Products").

12. 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

13. 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).

14. Venue is proper in this Court as to Granules India Ltd. because, among other things, Granules India Ltd. 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). Venue is proper in this Court as to Granules Pharmaceuticals, Inc. because it is a corporation incorporated in the State of Delaware. 28 U.S.C. § 1400(b).

PERSONAL JURISDICTION OVER GRANULES

15. Plaintiffs reallege paragraphs 1–14 as if fully set forth herein.

16. 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.

17. This Court has personal jurisdiction over Granules India Ltd. because, *inter alia*, Granules India Ltd., 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 Products to residents of this state upon approval of ANDA No. 220408, 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.

18. Alternatively, to the extent the above facts do not establish personal jurisdiction over Granules India Ltd., 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.

19. This Court has personal jurisdiction over Granules Pharmaceuticals, Inc. because Granules Pharmaceuticals, Inc. is a corporation incorporated under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

20. On April 24, 2018 the USPTO duly and legally issued United States Patent No. 9,949,998 ("the '998 patent") entitled "Pharmaceutical composition, methods for treating and uses

thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '998 patent is attached as Exhibit A. BII, BIC, and BIPI collectively own all right, title, and interest in and to the '998 patent.

21. On April 16, 2019, the USPTO duly and legally issued United States Patent No. 10,258,637 ("the '637 patent") entitled "Pharmaceutical composition, methods for treating and uses thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '637 patent is attached as Exhibit B. BII, BIC, and BIPI collectively own all right, title, and interest in and to the '637 patent.

22. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 ("the '323 patent") entitled "Pharmaceutical composition, methods for treating and uses thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '323 patent is attached as Exhibit C. BII, BIC, and BIPI collectively own all right, title, and interest in and to the '323 patent.

23. On December 5, 2023, the USPTO duly and legally issued United States Patent No. 11,833,166 ("the '166 patent") entitled "Pharmaceutical composition, methods for treating and uses thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '166 patent is attached as Exhibit D. BII, BIC, and BIPI collectively own all right, title, and interest in and to the'166 patent.

JARDIANCE®

24. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

25. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '998 patent, '637 patent, '323 patent, and '166 patent are among the patents listed in the FDA's Approved Drug

Products with Therapeutic Equivalence Evaluations database ("Orange Book") with respect to JARDIANCE®.

26. The '998 patent, '637 patent, '323 patent, and '166 patent cover the JARDIANCE® product and its use.

ACTS GIVING RISE TO THIS ACTION

27. 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.

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

29. Plaintiffs received a letter from Granules on or about April 17, 2025 (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 '998, '637, '323 and '166 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 '998, '637, '323 and '166 patents.

30. On information and belief, Granules does not dispute that the Granules ANDA Product will infringe the claims of the '998, '637, '323 and '166 patents in the Granules Letter.

31. Provided here as a representative claim for exemplary purposes, claim 1 of the '998 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m2 and <60 ml/min/1.73 m2, wherein empagliflozin is administered orally once daily as a pharmaceutical composition comprising 10 mg or 25 mg of empagliflozin, wherein the

glycemic control in said patient is improved, and discontinuing empagliflozin if the eGFR of the patient falls below 45 ml/min/1.73 m2."

32. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '637 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m2 and <60 ml/min/1.73 m2, wherein empagliflozin is administered orally in a total daily amount of 5 mg, 10 mg, 12.5 mg or 25 mg, wherein the glycemic control in said patient is improved, and discontinuing empagliflozin if the eGFR of the patient falls below 45 ml/min/1.73 m2."

33. Similarly, provided here as a representative claim for exemplary purposes, claim 1 of the '323 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m2 and <60 ml/min/1.73 m2, wherein empagliflozin is administered orally in a total daily amount of 10 mg or 25 mg, wherein the glycemic control in said patient is improved, and discontinuing empagliflozin if the eGFR of the patient falls below 30 ml/min/1.73 m2."

34. Finally, provided here as a representative claim for exemplary purposes, claim 1 of the '166 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising: a) assessing the renal function of the patient; and b) administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m2 and <60 ml/min/1.73 m2, wherein empagliflozin is administered orally in a total daily amount of 10 mg or 25 mg, and wherein the glycemic control in said patient is improved."

COUNT I — INFRINGEMENT OF THE '998 PATENT

35. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-34.

36. Granules has infringed at least one claim of the '998 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 '998 patent.

37. 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 '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

38. 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 '998 patent would further infringe at least one claim of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

39. 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 '998 patent either literally or under the doctrine of equivalents.

40. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '998 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '998 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.

41. 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 '998 patent, either literally or under the doctrine of equivalents.

42. On information and belief, Granules had knowledge of the '998 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 '998 patent, either literally or under the doctrine of equivalents.

43. 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 '998 patent, either literally or under the doctrine of equivalents.

44. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '998 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '998 patent.

45. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '998 patent.

COUNT II — INFRINGEMENT OF THE '637 PATENT

46. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–45.

47. Granules has infringed at least one claim of the '637 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 '637 patent.

48. 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 '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

49. 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 '637 patent would further infringe at least one claim of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

50. 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 '637 patent either literally or under the doctrine of equivalents.

51. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '637 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '637 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.

52. 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 '637 patent, either literally or under the doctrine of equivalents.

53. On information and belief, Granules had knowledge of the '637 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 '637 patent, either literally or under the doctrine of equivalents.

54. 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 ’637 patent, either literally or under the doctrine of equivalents.

55. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the ’637 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the ’637 patent.

56. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the ’637 patent.

COUNT III — INFRINGEMENT OF THE ’323 PATENT

57. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–56.

58. Granules has infringed at least one claim of the ’323 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 ’323 patent.

59. 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 ’323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

60. 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 ’323 patent would further infringe at least one claim of the ’323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

61. 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 '323 patent either literally or under the doctrine of equivalents.

62. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '323 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '323 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.

63. 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 '323 patent, either literally or under the doctrine of equivalents.

64. On information and belief, Granules had knowledge of the '323 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 '323 patent, either literally or under the doctrine of equivalents.

65. 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 '323 patent, either literally or under the doctrine of equivalents.

66. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '323 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '323 patent.

67. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '323 patent.

COUNT IV — INFRINGEMENT OF THE '166 PATENT

68. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–67.

69. Granules has infringed at least one claim of the '166 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 '166 patent.

70. 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 '166 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

71. 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 '166 patent would further infringe at least one claim of the '166 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

72. 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 '166 patent either literally or under the doctrine of equivalents.

73. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '166 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '166 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.

74. 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 '166 patent, either literally or under the doctrine of equivalents.

75. On information and belief, Granules had knowledge of the '166 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 '166 patent, either literally or under the doctrine of equivalents.

76. 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 '166 patent, either literally or under the doctrine of equivalents.

77. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '166 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '166 patent.

78. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '166 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 '998, '637, '323, and '166 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 '998, '637, '323, and '166 patents, and (ii) seeking, obtaining or maintaining approval of the Granules ANDA until the expiration of the '998, '637, '323, and '166 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. 220408 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 '998, '637, '323, and '166 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 the '998, '637, '323, and '166 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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