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,	)	C.A. No. _____
v.	)	
GRANULES INDIA LIMITED,	)	
Defendant.	)	

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 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' TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent Nos. 9,486,526 and 10,034,877.

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 ("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.

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

9. 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.

10. On information and belief, Granules prepared and submitted ANDA No. 219466 (the "Granules ANDA") for Granules' 5 mg linagliptin tablets (the "Granules ANDA Product").

11. 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

12. 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).

13. 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

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

15. 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.

16. 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. 219466, 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.

17. 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

18. On November 8, 2016, the United States Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 9,486,526 ("the '526 patent") entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Jurgen Woerle. A true and correct copy of the '526 patent is attached at Exhibit 1. Boehringer is the owner of all right, title and interest to the '526 patent, including the right to sue for infringement.

19. On July 31, 2018, the PTO duly and legally issued United States Patent No. 10,034,877 ("the '877 patent") entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Jurgen Woerle. A true and correct copy of the '877 patent is attached at Exhibit 2. Boehringer is the owner of all right, title and interest to the '877 patent, including the right to sue for infringement.

TRADJENTA®

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

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '526 and '877 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to TRADJENTA®.

22. The '526 and '877 patents cover the TRADJENTA® product and/or the use thereof.

ACTS GIVING RISE TO THIS ACTION

23. 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.

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

25. Plaintiffs received a letter from Granules on or about May 13, 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 '526 and '877 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 '526 and '877 patents.

26. On information and belief, Granules does not dispute that the Granules ANDA Product will infringe the claims of the '526 and '877 patents in the Granules Letter.

27. Provided here as a representative claim for exemplary purposes, claim 1 of the '526 patent recites: "1. A method for treating and/or preventing type 2 diabetes mellitus in a patient having moderate or severe chronic renal impairment or end-stage renal disease comprising orally administering to the patient 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, wherein said DPP-4 inhibitor is administered in an oral dose of 5 mg per day to said patient, wherein metformin therapy for said patient is ineligible due to contraindication against metformin."

28. Likewise, provided here as a representative claim for exemplary purposes, claim 1 of the '877 patent recites: "1. A method of treating metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient 5 mg of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine per day wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance, wherein no adjustment of the daily dose is required for 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a patient with mild, moderate or severe renal impairment or end-stage renal disease."

COUNT I — INFRINGEMENT OF THE '526 PATENT

29. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-28.

30. Granules has infringed at least one claim of the '526 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 '526 patent.

31. 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 '526 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

32. 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 '526 patent would further infringe at least one claim of the '526 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

33. 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 '526 patent either literally or under the doctrine of equivalents.

34. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '526 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '526 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.

35. 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 '526 patent, either literally or under the doctrine of equivalents.

36. On information and belief, Granules had knowledge of the '526 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 '526 patent, either literally or under the doctrine of equivalents.

37. 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 '526 patent, either literally or under the doctrine of equivalents.

38. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '526 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '526 patent.

39. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '526 patent.

COUNT II — INFRINGEMENT OF THE '877 PATENT

40. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–39.

41. Granules has infringed at least one claim of the '877 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 '877 patent.

42. 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 '877 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

43. 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 '877 patent would further infringe at least one claim of the '877 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

44. 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 '877 patent either literally or under the doctrine of equivalents.

45. On information and belief, the use of the Granules ANDA Product constitutes a material part of at least one of the claims of the '877 patent; Granules knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '877 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.

46. 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 '877 patent, either literally or under the doctrine of equivalents.

47. On information and belief, Granules had knowledge of the '877 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 '877 patent, either literally or under the doctrine of equivalents.

48. 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 '877 patent, either literally or under the doctrine of equivalents.

49. On information and belief, Granules does not deny that the Granules ANDA Product will infringe the claims of the '877 patent and in the Granules Paragraph IV Certification, Granules did not deny that the Granules ANDA Product will infringe the claims of the '877 patent.

50. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '877 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 '526 and '877 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 '526 and '877 patents, and (ii) seeking, obtaining or maintaining approval of the Granules ANDA until the expiration of the '526 and '877 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. 219466 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 '526 and '877 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 either of the '526 and '877 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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