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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND LIMITED
and ASSERTIO THERAPEUTICS INC.,

Plaintiffs,

v.

GRANULES INDIA LTD.,

Defendant.

Civil Action No. 19-14489

Document Electronically Filed

COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Ireland Limited (“Bausch Ireland”) and Assertio Therapeutics Inc. (“Assertio”) (collectively, “Plaintiffs”) for infringement of U.S. Patent Nos. 6,723,340 (the “’340 Patent”), 7,780,987 (the “’987 Patent”) and 8,323,692 (the “’692 Patent”) (collectively “Patents-in-Suit”) by Defendant Granules India Ltd. (“Granules” or “Defendant”), through the filing of Abbreviated New Drug Application (“ANDA”) No. 2133344 for the approval of Defendant’s generic version of Plaintiffs’ Glumetza® products described therein. Plaintiffs hereby allege as follows:

THE PARTIES

1. Plaintiff Bausch Ireland is a private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Assertio is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 S. Saunders Road, Suite 300, Lake Forest, Illinois 60045.

3. On information and belief, Defendant Granules is a pharmaceutical company organized and existing under the laws of India, with a principal place of business at 2nd Floor, 3rd Block, My Home Hub, Madhapur, Hyderabad 500 081, Telangana, India.

4. On information and belief, Granules together with its subsidiaries develops, manufactures, and markets pharmaceutical products in India, the United States, Europe and internationally.

NATURE OF THE ACTION

5. This is a civil action for infringement of the Patents-in-Suit. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

6. This is an action for patent infringement arising under the patent laws of the United States (Title 35 of the United States Code) and arising from Granules filing an ANDA with the United States Food and Drug Administration (“FDA”) seeking approval to market generic version of Plaintiffs’ Glumetza® prior to the expiration of the ’340, ’987 and ’692 Patents.

7. This action arises out of Granules filing ANDA No. 213344 (“Granules ANDA”) including its “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the Patents-in-Suit are invalid, unenforceable, and or will not be infringed by the commercial manufacture, use, sale, or importation of the Granules ANDA Products.

JURISDICTION AND VENUE

8. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Granules by virtue of, inter alia, the fact that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff in this District.

10. 9. This Court has personal jurisdiction over Granules for the further reasons that, inter alia, Granules (1) has substantial, continuous, and systematic contacts with this State, (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State, (3) intentionally markets and sells generic pharmaceutical drug products to residents of 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.

11. On information and belief, Granules USA, Inc. (“Granules USA”) is a subsidiary of Granules organized under the laws of New Jersey with its principal place of business at 35 Waterview Blvd, Parsippany, NJ 07054.

12. Upon information and belief, Granules USA is the North American division of Granules and is registered with the State of New Jersey as a drug wholesaler, under Registration No. 5003061.

13. Granules through its subsidiaries and various agents (for example Granules USA) offers generic pharmaceutical products for sale in New Jersey and elsewhere in the United States and earns revenue from the distribution and sale in New Jersey of its generic pharmaceutical products.

14. Upon information and belief, this Court has personal jurisdiction over Granules because, on information and belief, Granules will collaborate with Granules USA for the purposes of marketing and selling the Granules ANDA Products once approved by the FDA.

15. Upon information and belief, Granules conducts business through and with Granules USA, its wholly owned subsidiary. Granules has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. Granules directly or through its affiliates and agents, such as Granules USA, develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the Granules ANDA Products in New Jersey.

16. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Granules pursuant to Federal Rule of Civil Procedure 4(k)(2) because Granules has extensive contacts with the United States, including but not limited to the above-described commercial contract, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Granules is consistent with the laws of the United States and the United States Constitution.

17. Venue is proper as to Granules because it is a foreign defendant and can be sued in any district.

THE PATENTS-IN-SUIT

18. On April 20, 2004, the '340 Patent entitled "Optimal Polymer Mixtures for Gastric Retentive Tablets" was duly and legally issued. The named inventors of the '340 Patent are Gloria Gusler, Bret Berner, Mei Chau, and Aimee Padua. According to the Orange Book, the expiration date of the '340 Patent is October 25, 2021. (A copy of the '340 Patent is attached as Exhibit 1.)

19. Assertio is the assignee of the '340 Patent.

20. On August 4, 2010, the '987 Patent entitled "Controlled Release Dosage Forms" was duly and legally issued. The named inventors of the '987 Patent are Fang Zhou and Paul Maes. According to the Orange Book, the '987 Patent expires on March 23, 2025. (A copy of the '987 Patent is attached as Exhibit 2.)

21. On December 4, 2012, the '692 Patent entitled "Controlled Release Dosage Forms" was duly and legally issued. The inventor of the '692 Patent is Steven Frisbee. According to the Orange Book, the '692 Patent expires on March 30, 2023. (A copy of the '692 Patent is attached as Exhibit 3.)

22. Bausch Ireland is the assignee of the '987 Patent and the '692 Patent.

ACTS GIVING RISE TO THIS ACTION

23. Santarus Inc. holds the approved New Drug Application No. 21748 for Glumetza® 500 mg and 1 gm dosage strengths.

24. Pursuant to 21 U.S.C. § 355(b)(1), the '340 Patent is listed in Orange Book for Glumetza® 500 mg and the '987 Patent and the '692 Patent are listed in the Orange Book for Glumetza® 1 gm.

25. On information and belief, Granules submitted the Granules ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of the Granules 500 mg product and Granules 1000 mg product, herein collectively referred to as the "Granules ANDA Products."

26. Plaintiff received from Granules a letter, dated May 21, 2019, (the "Granules Notice 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 the '340, '987 and '692 Patents are invalid, or will not be

infringed by the commercial manufacture, use, or sale of the Granules ANDA Products (the “Paragraph IV Certification”).

27. The Granules ANDA refers to and relies upon the Glumetza[®] NDA and contains data that, according to Granules, demonstrate the bioequivalence of the Granules ANDA Products and Glumetza[®].

28. This action was commenced by Plaintiff within 45 days of the date of receipt of the Granules Notice Letter.

CLAIMS FOR RELIEF

COUNT I (Infringement of the '340 Patent)

29. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

30. On information and belief, Granules has infringed at least one claim of the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Granules ANDA, by which Granules seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Granules ANDA Products prior to the expiration of the '340 Patent.

31. Moreover, if Granules manufactures, uses, sells, offers for sale, or imports into the United States, the Granules ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '340 Patent, including any applicable exclusivities or extensions, Granules would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '340 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Granules ANDA be a date that is

not earlier than the expiration of the term of the '340 Patent, including any extension(s) granted by the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '340 Patent to which Plaintiffs are or become entitled.

33. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '340 Patent.

34. Plaintiffs have no adequate remedy at law.

35. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Infringement the '987 Patent)

36. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

37. On information and belief, Granules has infringed at least one claim of the '987 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Granules ANDA, by which Granules seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Granules ANDA Products prior to the expiration of the '987 Patent.

38. Moreover, if Granules manufactures, uses, sells, offers for sale, or imports into the United States, the Granules ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '987 Patent, including any applicable exclusivities or extensions, Granules would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '987 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Granules ANDA be a date that is

not earlier than the expiration of the term of the '987 Patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '987 Patent to which Plaintiffs are or become entitled.

40. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '987 Patent.

41. Plaintiffs have no adequate remedy at law.

42. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
(Infringement of the '692 Patent)

43. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

44. On information and belief, Granules has infringed at least one claim of the '692 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Granules ANDA, by which Granules seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Granules ANDA Products prior to the expiration of the '692 Patent.

45. Moreover, if Granules manufactures, uses, sells, offers for sale, or imports into the United States, the Granules ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '692 Patent, including any applicable exclusivities or extensions, Granules would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '692 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

46. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Granules ANDA be a date that is

not earlier than the expiration of the term of the '692 Patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '692 Patent to which Plaintiffs are or become entitled.

47. Plaintiffs will be substantially and irreparably harmed if Granules is not enjoined from infringing the '692 Patent.

48. Plaintiffs have no adequate remedy at law.

49. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek relief as follows:

1. A judgment that Granules has infringed one or more valid claims of the '340, '987 and '692 Patents by submitting or causing to be submitted the Granules ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Granules ANDA Products before the expiration of the Patents-in-Suit;

2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Granules, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Granules ANDA Products within the United States, or importing the Granules ANDA Products into the United States, prior to the expiration of the Patents-in-Suit;

3. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Granules ANDA 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 '962, '340, '987 and/or '692 Patents, including any extensions;

4. A judgment declaring and enjoining Granules, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Granules ANDA Products and any other product that infringes or induces or contributes to the infringement of one or more claims of the Patents-in-Suit prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

5. That Plaintiffs be awarded damages for their costs, disbursements, expert witness fees, and attorneys' fees and costs incurred in prosecuting this action, for an exceptional case pursuant to 35 U.S.C. § 285 and as otherwise provided by law; and

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

Dated: June 28, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: June 28, 2019
Newark, New Jersey

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